
IN THE
United States Court of Appeals
FOR THE NINTH CIRCUIT.

No. 15373

CARTER PRODUCTS, INC.,
Petitioner,

against

FEDERAL TRADE COMMISSION,
Respondent.

REPLY BRIEF OF PETITIONER.

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REPLY BRIEF OF PETITIONER.

A.

The Commission's Brief amounts in effect to an abandonment on its part of any effort to refute, and to an admission of the irrefutable force of, the Petitioner's Specific Challenges to the Commission's Findings and Order concerning Petitioner's product claims of increasing bile flow and Petitioner's contentions of denial of due process.

The Commission's Brief makes no genuine attempt to answer the Petitioner's specific charges (a) of outright denials by the Commission to this Petitioner of due process, (b) of the plain bias and prejudgment of the issues by the Commission and its Examiner and their refusal to make any fair estimate of the worth of opposing evidence, (c) of the clear reversible error in the application by the

Commission of erroneous and dual standards of proof,* (d) of the Commission's violations of "fair play" which is the essence of due process (*Galvan v. Press*, 347 U. S. 522, p. 523), in repetition and intensification of the same or similar unfair practices of the Commission condemned by this Court in its prior opinion in this case, (e) of the Commission's Examiner's blocking of the proper examination of key witnesses (f) of the Commission's flouting of the spirit of this Court's remand and (g) of the Commission's total failure to establish its affirmative case by the fair preponderance of substantial evidence, all fully documented in Points I and II of Petitioner's Opening Brief.

As to the remarks (Commission's Brief, pp. 62-63), concerning the Petitioner's alleged failure to make "proper"*** application to introduce the Twiss experiments demonstrating the truth of all of Petitioner's bile flow claims by his exhaustive scientific tests carefully conducted in accordance with proper and up to date scientific procedures,*** Petitioner's answer is plainly set out in Subds. D and E, pp. 134-146 of Petitioner's Opening Brief—to which the Commission's Brief makes no effective reply—to wit, that, as demonstrated in Petitioner's Briefs, on the record here shown, introduction or leave to make introduction of this new and unanswerable body of evidence before this Exam-

* Receiving, as an added instance of discrimination, hearsay evidence to bolster the Commission's own witness, Dr. Case (Opinion, Vol. I, N. R. 321) but rejecting Petitioner's many proffers in its Offers of Proof (*id.* 33-66) of similar evidence in the form of authoritative scientific textual authorities in support of Petitioner's witnesses.

** See p. 3 Petitioner's Supplemental Brief on Appeal to the Commission, dated May 11, 1956.

*** See Vol. I, N. R. Offers of Proof and Twiss affidavit, pp. 33-66, particularly pp. 43-46, and Petitioner's Ex. for Id. No. 3, all rejected by the Examiner. Because of the importance in this case of Petitioner's Motions and Offers of Proof, the Court is respectfully urged to examine them in full.

iner, whose disqualifying bias and prejudgment of this case have now been established beyond the peradventure of a doubt, *would constitute the merest empty gesture neither affording the Petitioner due process nor any real or adequate remedy whatsoever.*

The Commission's Brief makes no attempt to answer specifically all the other self-evident, virtually admitted, and fatal defects in the Commission's evidence and experimental proof which because of the Commission's bias it ignored, nor any attempt at all to controvert the Petitioner's formidable constitutional objection based on the legislative history of the Wheeler-Lea Amendments to the Federal Trade Commission Act set out in Point III of Petitioner's Opening Brief. In this connection, added, for instance, to all the many other sharp rifts and unresolved differences in general medical opinion itself on major issues in this case disclosed by this record, some of which were conceded by the Commission's own witnesses, (Point III, *supra*, pp. 153-4) and which type of difference in general medical opinion, for the cogent reasons there set forth, *deprives the Commission of any power at all to issue a Cease and Desist Order in this case*, is this further concession by the Commission's key witness, Dr. Palmer: This witness for the Commission in effect conceded (Vol. II, N. R. Palmer 651-653) the existence in regard to one of the most vital issues in this whole suit, namely, as to whether there are certain conditions of the liver (biliary dyskinesia,* for example) which Petitioner contends are improved by a better flow of bile, that there is a "*difference of medical opin-*

* See the authoritative statement of Dr. Henry L. Borkus, Professor of Gastroenterology, University of Pennsylvania Graduate School of Medicine, in his work "Gastro-enterology" (1946) that in this recognized condition "frequent emptying of the biliary tract should be encouraged," corroborating Dr. Morrison, but rejected by Commission and Examiner (Offers of Proof Vol. I, N. R. pps. 57, 61).

ion'' (*id.* 652). Here, again, also, as the Court will see, (*id.* 653) the Petitioner was prejudicially blocked by the Commission's Examiner from proper further exploration, by cross examination of this witness, of further differences of medical opinion (which the witness appeared to indicate were "great", *id.* 653) as *applied* to the "*gastro-intestinal and biliary systems*" *generally*. This restriction of cross examination on so important an issue was in itself reversible error and denial of due process, *Alford v. U. S.*, 282 U. S. 687, pp. 691-2; *Reilly v. Pinkus*, 338 U. S. 269, pp. 275, 276.

By its failure specifically to answer, the Commission in effect admits, the irrefutable force of all of Petitioner's major contentions on this Appeal of the Commission's and its Examiner's bias and its denials of due process and reversible errors.

B.

The detailed refutation (which for its protection Petitioner has been obliged to make) in Appendix "A" of this Reply Brief of the amazing array of material misstatements, omissions and distortions contained in the Commission's Brief and the analysis in that Appendix of numerous further denials of due process by the Commission constitute further demonstration of Petitioner's clear right to the relief Petitioner seeks on this Appeal.

Instead of attempting to meet Petitioner's justified attacks upon the Commission's Findings and upon its and its Examiner's improper conduct of this case, the Commission in its Brief resorts in desperation to a running series of material omissions, distortions and misstatements (and to spurious charges of misstatements by Petitioner) of such

an extreme and extensive nature that Petitioner cannot, by leaving them unchallenged, run the grave risk of this Court's being misled by these tactics on the Commission's part.

Petitioner is, therefore, forced, both for the positive protection of its rights and also in order to avoid any implication of admissions on its part similar to the implication which arises because of the Commission's failure specifically to answer Petitioner's contentions, to refute those misstatements *seriatim*. Such detailed refutation and numerous instances of still further denials of due process on the Commission's part necessarily involved in that refutation are contained in Appendix A. The matters there set forth are of real substance and of such extremely vital importance to Petitioner's case that this Court is most earnestly and respectfully requested to read the Appendix in its entirety, among other reasons because the misunderstandings and fundamental mistreatments of the evidence in which, even in its Brief, the Commission still persists are further eloquent proofs of its bias and prejudgment.

The present appeal brings up for review by this Court all the reversible errors which lurk in this entire Record not *specifically* passed upon by this Court's former limited review. This Court's prior reversal of the Commission is not "an adjudication by the appellate court of any other than the questions in terms *discussed and decided*". * * * "All questions which appear upon the record *and have not already been decided are open for consideration*", *Mutual Life Ins. Co. v. Hill*, 193 U. S. 551, pp. 553-4; *Hartford Life Ins. v. Blincoe*, 255 U. S. 129; *Wolff Packing Co. v. Industrial Court*, 267 U. S. 552; *American Cyanamid Co. v. Wilson and Toomer Fertilizer Co.*, 51 F. (2) 665. As this Court held in *Hansen & Rowland v. C. F. Lytle Co.*, 167 F. (2) 998, p. 999, "a judgment of reversal by an appellate

court is an adjudication *only of matters expressly discussed and decided * * *.*” To the same effect *McLain Lines v. The Ann Marie Tracy*, 176 F. (2) 709, p. 711; *U. S. v. U. S. Smelting Co.*, 339 U. S. 186, p. 198.

C.

The assertions in the Commission’s Brief pages 12-14 that the contested issues on this appeal are confined to Petitioner’s bile flow claims are without substance or support.

Furthermore, the Commission’s findings on all the other issues in this case are equally contrary to the evidence and are further so intermingled with, and infected by, the invalidity of its findings on the issues of bile flow and constipation that they must likewise be set aside.

Not only do Petitioner’s Statement of Points (Vol. VIII, N. R., pp. 3540-3556) and its Petition For Review (Vol. VIII, N. R., pp. 3531-3539) bring up for review all the other issues in this case but, in addition, Petitioner’s Designations, dated February 15, 1957, filed with this Court, themselves fairly and squarely contain the following plain notice to the Commission apprising it of that fact:

“2. . . Petitioner begs leave to furnish the Court with 10 printed copies of the Petitioner’s Original Printed Exceptions To The Trial Examiner’s Original Report and its original printed Proposed Findings of Fact, all dated October 15, 1946, a printed copy of which was filed of record in the former proceedings (and copies of which have previously been furnished to the Respondent) *for use on this review, in lieu of reprinting those exceptions and proposed findings; and Petitioner notifies the Respondent that it intends to rely on the matters and things of record and the excerpts from the testimony and transcript*

*set forth in those printed exceptions and proposed findings as further basis for its Petition to Review and Set Aside the Respondent's Cease and Desist Order.''**

The reasons why the Commission is not entitled to have this Court sustain *any* of the provisions of its Order (see those specifically referred to, p. 14 of the Commission's Brief) and the supporting references to the testimony of Petitioner's witnesses, Drs. Avrack, Boyd, Colbert, Darling, Edlin, Leader, Lindauer, Lopez, Lyon, Steigmann, Whittemore, O'Brien, Allen, Bastedo, Johnson, Eller, Dorman, Sandford and Loewe which demonstrate the truth of *all* Petitioner's therapeutic and advertising claims are set forth at pages 3-5 and 9 of Petitioner's Original Printed Exceptions and at pages 143, 147-148, 191-196 of Petitioner's Original Proposed Findings of Fact, all dated October 15, 1946 (Vol. IX, N. R., at p. 3557) and at pages 170-201 of Petitioner's Original Brief, dated February 1, 1947, which is also a part of the transcript of proceedings filed with this Court, extra copies of which are available for its use.

It has been literally and physically impossible, because of space limitations, to give treatment to these other issues in Petitioner's Opening Brief and in this Reply Brief. The Court is therefore respectfully referred to the treatment at length of these other issues in the documents and brief referred to. From an examination of these documents, the truth of all of Petitioner's advertising claims will, Petitioner respectfully asserts, fully appear.

Furthermore concerning these assertions in the Commission's Brief (p. 14) to the effect that the Commission is entitled to a decree affirming all other findings of fact except

* See also pp. 9-10, Petitioner's Opening Brief.

those relating to Petitioner's bile flow claims, and that the Commission is also entitled specifically to a decree enforcing certain specified provisions of the Commission's Cease and Desist Order, there is a further simple answer. Those other Findings and those specific provisions of the Commission's Order, besides being contrary to the weight of evidence as shown by the evidence and documents referred to above, are also, as this Court will see by examining those provisions of the Order, so inextricably inter-related and intermingled with Petitioner's bile flow claims and the Petitioner's claims concerning the relationship between constipation and bile flow that those other Findings and provisions of the Order must also of necessity likewise fall with the falling and setting aside of the Commission's Findings and the provisions of its Order concerning these basic bile flow and constipation claims of the Petitioner.

Subdivision (1) of the Commission's Order (Vol. I, N. R., p. 312) which forbids advertising "That constipation poisons the body" is in effect in virtual conflict with the logic of the testimony of the Commission's own witness, Dr. Carlson, whom the Commission's Brief (p. 29) describes as "one of the greatest physiologists in the world." This witness for the Commission, though obviously equivocating as to constipation's being poisonous, flatly asserted, however (Vol. I, N. R. Carlson, p. 388), that constipation was a disease and "that constipation can be so chronic and the absorption of water from the fecal material so great, it becomes dry, and in the end *causes local ulcers and local sores and lesions and bleeding * * **" and (Vol. I, O. R. 379, Carlson) that if "digestible and unabsorbed food have gotten down into the large bowel and stayed there because of *constipation*, there would be some *bacterial* action on it"—deleterious effects which are cer-

tainly at least comparable to poisoning the body.* The Commission's notion that constipation does not result in the growth of the poisons—phenol, indol, or skatol—(Vol. IV, O. R. 1418-19, Bollman; Vol. VI, N. R. 2494, Bollman) is further derived from the dog experiments of Bollman whose hopelessly vitiating defects have been shown. In fact Bollman conceded (Vol. IV, O. R. 1452) that an ingredient of his diet for these dogs had a protective action against these very poisons. This is but one instance of the futility of trying to separate the void and partly void intermixture of findings which the Commission has made in this case. Excluded by the Commission in this connection is the pertinent statement contained in Petitioner's Offer of Proof (Vol. I, N. R. p. 64) of Dr. John A. Wolfer that "*Constipation* may predispose an individual to gallstone formation because of *intestinal infection* and secondary cholecystic disease. Kraus reported that 80% of patients with gallstone were constipated"—a statement again indicative of an effect comparable to poisoning the body.

Subd. (h) of the Order (Vol. I, N. R., p. 312) forbids advertising "That said preparation will cause the proper flow of, or beneficially affect, the gastric juices or digestive juices." Here again, despite equivocations on his part, the Commission's witness, Dr. Ivy, nevertheless, testified (Vol. II, O. R. Ivy 538-539) that Carter's Little Liver Pills would increase the volume of the most important digestive juice, increase the bulk in the small intestine, increase the peristaltic movements, etc. (*id.* 539). *It is true that Ivy also claimed that this admitted action of the pills was not in his opinion beneficial. However, the credibility evaluations made by the Commission have been shown to have been*

* See also the uncontradicted testimony of Petitioner's witness, Dr. McGuigan (Vol. III, N. R. 882), ignored by the Commission in its Findings, that constipation may cause "ulceration", "inflammation", "hernia", or "even cause angina pectoris or apoplexy by straining".

so deficient and Ivy's testimony and experiments have been shown to have been so defective and untrustworthy that there is no reason to trust Ivy's attempts to discredit the beneficial nature of this admitted effect of Petitioner's product. Further, here again, the Commission neither took proper note of the testimony of the Petitioner's witnesses, Drs. Crandall (N. R. Vol. VII, 2898-2900) and McGuigan (N. R. Vol. II, 833-871; N. R. Vol. III, 938-9) as to the value of cathartics and laxatives and their safety, nor of the testimony to that effect of Petitioner's witnesses, Drs. Avrack, Boyd, Colbert, Darling, Edlin, Leader, Lindauer, Lopez, Lyons, Steigmann, Whittemore, O'Brien, Allen, Bastedo, Johnson, Eller, Dorman, Sanford and Loewe, supporting references to whose testimony in the original transcript certified to and on file with this Court are set forth at pages 3, 5, 9 of Petitioner's Original Printed Exceptions, dated October 15, 1946, and at pages 143, 147-148, 191-196 of Petitioner's Original Proposed Findings of Fact dated October 15, 1946 (N. R. Vol. IX at p. 3557) and in Petitioner's Original Brief, pp. 170-201, filed with the Commission.

Subd. (d) of the Commission's Order (*id.* 312) forbids advertising "That said preparation is unqualifiedly safe". Of course, as appears from Petitioner's Original Proposed Findings p. 196, Petitioner has included in its labeling for years the following statement:

"Important Warning—In cases of symptoms of appendicitis such as vomiting, severe abdominal pains or nausea, do not take Carter's Little Liver Pills or any laxative. See your physician. Carter's Little Liver Pills are to be taken only as needed and should not be used habitually."*

* See also Petitioner's Opening Brief, p. 106, and Commission's Ex. 1-B there referred to, for similar *qualifications* in Petitioner's directions for use of its product.

There has thus never been a claim by Petitioner that its product is “*unqualifiedly* safe”.

The other specific provisions of the Order to which the Commission here makes reference (its Brief, p. 14) are, as this Court will see by examining them, too obviously inter-related with Petitioner’s bile flow and constipation claims and the Commission’s invalid Findings concerning these claims to require discussion.

In general, as was to be expected from the Petitioner’s showing of the Commission’s bias and denials of due process in connection with its treatment of Petitioner’s bile flow and constipation claims, the Commission likewise *applied* (as this Court will see by examining the record references cited above and their discussion in Petitioner’s Original Brief of Feb. 1, 1947) the *same* disqualifying fixed prejudgment and *similarly* biased treatment to all these *other* issues.

D.

Conclusion.

On all the grounds set forth in Petitioner’s Opening Brief and in this Reply Brief and Appendix and because of the Commission’s flouting of the spirit and purpose of this Court’s remand,* Petitioner respectfully requests that this Court reverse and set aside the Commission’s Order in its entirety and thereby put an end to the fourteen long years of harassment and expense and to the unjust and adverse publicity to which Petitioner and its product have been subjected and also to the public waste caused by this ill-starred

* “after the remand was made therefor the Commission was bound to deal with the problem afresh”, *Securities Commission v. Chenery Corp.*, 332 U. S. 194, p. 201.

and senseless litigation which, to use the words of Judge Medina in *Prima Products Inc. v. Federal Trade Commission*, 209 F. (2d) 405, p. 406, now “bears a marked resemblance to the proverbial tempest in a teapot.”

Dated: December 6, 1957

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APPENDIX A.

Material Misstatements, Omissions and Distortions Contained in the Commission's Brief Refuted, and Further Instances Demonstrated of the Commission's Denials of Due Process.

1. At the risk of creating the possible impression in the mind of this Court that the use of podophyllum (one of the ingredients of Petitioner's pills) is officially wholly disapproved, the Commission (Commission's Brief, p. 15) asserts that "Podophyllum has been removed from the U. S. Pharmacopeia". The Commission well knows, and this Court may take judicial notice of the fact,* suppressed by the Commission's Brief, that podophyllum was officially reinstated to the U. S. Pharmacopeia and now appears in the Fifteenth Revision at p. 560 of that official compendium as of December 15, 1955.

2. The Commission asserts (Commission's Brief p. 16) "if there is an impairment or a disease of the liver which *cuts the production of bile*** to 80% there still *would remain* sufficient bile for the proper digestion of fat food (R. 12940, Vol. IV, 1417-18, 1478)". This reference is to testimony of the Commission's witness, Bollman. What Bollman actually said was absurd enough, i.e.:

"Q. Doctor, in your opinion, to what extent may the human liver be damaged and still produce sufficient bile to carry on the functions of bile in the process of human digestion? A. I should say that somewhere around eighty percent of the liver could be absent or severely damaged and yet the liver maintain sufficient bile output to carry out the process of digestion" (Bollman, O. R. Vol. IV, p. 1417).

* See authorities, p. 31 of Petitioner's Opening Brief and, *infra*, end of this Appendix.

** Italics ours throughout, unless otherwise noted.

Bollman did not, however, say, what is quite a different matter, i.e., that *production of bile itself may be reduced by that percentage*. This is clear from Bollman's explanation (Bollman, *id.* p. 1417) that "If part of the liver was removed, there is a *new growth in the remaining liver, so that there is essentially a replacement thereby, overcoming the lack of function that may have been implied in the removal of part of the liver*".

More serious is the Commission's omission of all reference in its Brief to the following flat denial of due process committed by the Commission through its Examiner. By this denial of due process, Petitioner was deprived of its clear right to *rebut* Bollman's testimony, by showing through Petitioner's own witness, Dr. Morrison, that no human being had ever been known to function normally with 80 % of his liver absent or severely damaged.

The Commission's Examiner thwarted all legitimate inquiry of Dr. Morrison by Petitioner in this vital area, as follows (Morrison Vol. IV, N. R. 1601-1602):

"By Mr. Hanaway:

"Q. Do you know of any cases, ambulatory cases of individuals whose livers are defective to the extent of 80 per cent?

"Mr. Cohn: Objection.

"Trial Examiner Purcell: I believe it is proper redirect.

"Mr. Hanaway: Because Mr. Cohn asked him on cross about the possibility of liver disorder or incapacity to the extent of 80 per cent.

"Trial Examiner Purcell: You are now seeking to elicit the Doctor's knowledge as to ambulatory cases.

"Mr. Hanaway: With livers. I want to know if there is anybody who has a liver which has been destroyed to the extent of 80 per cent, who is not a museum piece or a monstrosity of some kind.

“Mr. Cohn: Of course, if your Honor please, I made special emphasis on what the Doctor knows.

“Mr. Hanaway: Are these hypothetical questions or are there actual persons walking around whose livers are not there? In other words, the question is of no importance on cross examination.

“Trial Examiner Purcell: Let us have the question.

(The question referred to was read by the reporter, as follows:

“Q. Do you know of any cases, ambulatory cases of individuals whose livers are defective to the extent of 80 per cent?’’)

“Mr. Cohn: Objection.

“Trial Examiner Purcell: Objection sustained.

“Mr. Hanaway: May I ask your Honor’s basis for that.”

“Trial Examiner Purcell: In the first place, the Doctor has stated that there is no way that he can ascertain the percentage of damage incurred in any particular liver, even by functional tests. *I apprehend* that the only way he could ascertain that would be by biopsy and histological examination.

“Mr. Hanaway: I would like to have the witness testify.

“Trial Examiner Purcell: You asked for my reason.

“Mr. Hanaway: I would like to have the witness testify.

“Trial Examiner Purcell: I have given my reasons and I sustain the objection. * * *”

No further comment is necessary!

The right of rebuttal is a fundamental constitutional right. Its denial is a denial of due process. Admission of rebuttal evidence is *not* a matter of discretion; it is a matter “of strict right,” *Throckmorton v. Holt*, 180 U. S. 552, 565. Its denial is reversible error. As a matter of constitutional

right a party must be given an opportunity "to offer evidence in *explanation* or *rebuttal*," *Int. Com. Commission v. Louisville & Nashville R. R. Co.*, 227 U. S. 88 page 93; *Ankersmit v. Tuck*, 114 N. Y. 51 page 55. This applies to all of the other incidents of similar refusals by the Commission of Petitioner's right of rebuttal or *explanation* set out in this Reply Brief and in Petitioner's Opening Brief.

Again, in this connection, no reference is made in the Commission's Brief to its and its Examiner's erroneous rejection of Petitioner's Offer of Proof (Vol. I N. R. p. 44) of the statement in Dr. Twiss's* article, page 194, (Petitioner Ex. for Id. No. 3), in rebuttal in general of Bollman and other witnesses of the Commission, that "Results obtained in healthy *ambulatory* patients are preferable to those obtained in sick bed patients, *particularly those recently subjected to operative procedures involving alterations in the biliary duct.*"

3. The Commission states (Brief, p. 16) "an individual does not require the production of two pints of bile daily to prevent digestive disturbances (R., 12940, Vol. II, 671-674, 1557)." Again, what the Commission fails to disclose to this Court is that its own witness, Dr. Walter Lincoln Palmer (Palmer, Vol. II, N. R., 646-647), whose formidable list of qualifications consumes some two pages of the Examiner's Original Report (O. R., Vol I, pp. 283-4), on reading the statement from Petitioner's advertising as to the liver that, "its job is to pour two pints of bile juices a day into your bowels, to help digest your food, to help in stopping its unnatural decay and to help your bowels to move softly, naturally, fully", answered (N. R., Vol. II, pp. 646-648), "*That is, in the main, true*". Again, on reading Petitioner's advertising statement that (*id.* 648) "the liver should pour out two pounds of liquid bile on to the food you swallow each day," the Commission's

* Dr. Twiss's authoritativeness was recognized by the Commission's witness, Bollman, on the remand (Vol. VIII, N. R. 3223; Petitioner's Opening Brief, pp. 73, 75-6).

witness, Dr. Palmer also answered “*That is approximately correct*”.*

4. The Commission states (Brief, p. 16):

“We believe it is equally important to invite the Court’s attention to the *fact* that there is no evidence of *any nature* in the record that *any* doctor has *ever prescribed* petitioner’s laxative pill for any purpose other than to produce an evacuation of the bowels.”

Of course, the actual fact is that Petitioner’s witness, Dr. Morrison, (Morrison, Vol. IV, N. R., 1600-1601) testified on redirect:

“By Mr. Hanaway:

“Q. You stated during cross-examination that Carter’s Little Liver Pills were not a primary treatment for *biliary dyskinesia*. What did you mean by that? A. I meant that the drug was not used primarily in this condition, but that it might have a therapeutic effect if used when *this condition was associated with chronic constipation*.

“Q. *Is it frequently association (sic) with chronic constipation?* A. *I believe it is.*

“Q. Do you use aloes and podophyllum as routine *stimulants* in biliary drainage in your office? A. *I do now*”.

Even the Commission’s witness, Dr. Palmer, when asked by the Commission’s Counsel whether he had “ever heard of a doctor using aloes and podophyllum, Carter’s Little Liver Pills, for the purpose of increasing the flow of bile”, answered: “I have heard of them doing it, yes, they think they do it” (Palmer, Vol. II, O. R., 696).

That there is not a great deal more evidence in this record of the prescription by eminent doctors of aloes and podophyllum, the ingredients of Carter’s Little Liver Pills,

* Medicine as an inductive science is itself “a field of knowledge where even experts must be content with *approximations* to verity”; *Scientific Mfg. Co. v. F. T. C.*, 124 F. (2) 640 p. 644.

and of the therapeutic value of those drugs in increasing bile flow is due to the fact (which again the Commission in its Brief omits to state) that its Examiner and the Commission also excluded, among other things, the following:

Statements by Dr. Martin Rehfuss, recognized as an authority on the subject by Commission's witness, Bollman (Bollman, Vol. VIII, N. R. 3212) in Dr. Rehfuss' authoritative book, with which Bollman swore he was familiar, (*id.* 3212), "The Medical Treatment of Gallbladder Disease", Chapter XVI (Petitioner's Exs. 8 and 9, for Id. appended to its Offer of Proof, Vol. I, N. R. pp. 46, 47, 54, 61) specifically attesting to the therapeutic value and use of podophyllum as a vegetable chologogue (p. 289):*

"The so-called 'vegetable' cholagogues include many substances, *aloes, podophyllin, boldo, euonymin*, frequently found in laxative and cathartic pills. * * * *Podophyllin* is part podophyllotoxin and part picropodophyllin. *Its action is to empty the liver radicles and fill the biliary passages.* * * * *We have used all these substances* * * *."

This was not one of the texts as to which Petitioner was permitted actually to cross examine Bollman. It was an authority discovered thereafter, *but while the proceedings were still open, and it was as aforesaid included in Petitioner's rejected Offer of Proof*** made in accordance with Petitioner's arrangement with the Examiner.

5. Four pages of the Commission's Brief (pp. 17-20) are devoted to maligning Petitioner for making what Petitioner asserts is, on the contrary, an obviously true interpretation of the effect of the testimony of the Commission's witnesses, Ivy and Carlson. The plain fact is, despite the Commission's attempts at palliation, that Ivy published an article with regard to the common duct fistula method, a method which Ivy used in his abnormal dog experiments (whose description by the Examiner is

* See p. 290, same Ex. for Id. prescribing podophyllum.

** Vol. I, N. R., pp. 46, 47, 54, 61.

set out in Petitioner's Opening Brief, pps. 13-14), in which Ivy said (Vol. II, N. R. 683-5) that with a duodenal or common duct fistula "the physical conditions are *entirely changed, a fact that has been disregarded too frequently*" and conceded on cross examination that it creates "a disturbance and (sic) of possible creation of *abnormal* difference in pressure." (*id.* 684-5).

That the Commission's charges against Petitioner in this regard are without any real substance and that the surgical fistula methods used by Commission's witness Ivy did in fact create an *abnormal* condition as Petitioner maintains they did, are proved out of Ivy's own words quoted by the Commission itself (Commission's Brief, p. 31), "Dr. Ivy explained", says the Commission, "that bile *normally flows into our intestines, and in the experiment in Table I (CX97) there was no bile in the intestine * * **". Of course, there was no bile flowing into the intestines in Ivy's fistula experiments, as Ivy himself testified was the *normal and proper way for bile to flow*, because, with a surgical fistula, bile is cut off and diverted (into a bag or cylinder where it is collected) from its normal course of flow into the intestines *which it never reaches*. The Examiner in effect so states in his description of Ivy's fistula method (Paragraph 106, Examiner's Original Report, p. 98, Vol. I, O. R.).

Obviously, also, it is the general gist of the Commission's witness, Carlson's testimony (and that is all that Petitioner intended in its opening Brief to imply) that where the bile "*does not get into the intestine in the normal way*" it has "*a bad effect in the way of injuring the liver*" (Carlson Vol. I, N. R. 344-5). As the Court will see, it is eminently reasonable to apply that testimony of Carlson's to the abnormal situation created by Ivy in his surgical bile fistula dog experiments.

In this connection, here again, no reference is made by the Commission in its Brief to the testimony (confirmatory of Petitioner's interpretation) of Petitioner's witness, Dr. Morrison (Petitioner's Opening Brief, footnote p. 15 and pp. 138-139) as to the disturbing factor of surgical opera-

tions on the biliary tract which are present in the case of bile fistulas. Neither is there reference in the Commission's Brief to the authoritative statements contained in the article, which article is referred to in Dr. Twiss' affidavit (Vol. I, N. R. p. 59), *co-authored by Drs. Snell and Butt, Dr. Bollman's former associates at Mayo Clinic* (Bollman, Vol. VIII, N. R. 3175), being Petitioner's Ex. for Id. No. 13 p. 19 appended to Petitioner's Offer of Proof excluded by both Examiner and Commission. Those statements, indicative of the abnormal effect of bile fistulas, are that "The *exclusion* of bile from the intestinal tract *results in incomplete* digestion and *absorption* of fats and probably in some *deficiency* in the absorption of fat-soluble vitamins and calcium". Neither is there any reference in the Commission's Brief to the statement of the same Dr. Martin Rehfuss who was recognized by Bollman as authoritative (a statement likewise so excluded by the Commission and Examiner) in his "A Study of the Third Bile Fraction" Vol. 8, American Journal of Digestive Diseases, Nov. 1941, pp. 407-415, Petitioner's Ex. for Id. No. 7, p. 410, regarding studies "*made on fistula bile which can hardly be considered normal*". Again these were not textual authorities as to which Petitioner was permitted to cross examine Bollman, but again they were discovered thereafter *but while the proceedings were still pending, and were also included in Petitioner's rejected Offer of Proof*.

It is further a matter of plain fact and common sense, that these surgical procedures of Ivy's—particularly when all the other disturbing variables discussed in Petitioner's Point I, pp. 13-44 of its Opening Brief are also considered—obviously upset these test animals' metabolisms and nullified the Commission's tests just as Judge Woolsey held that the government's tests were nullified in *U. S. v. 59 Tubes*, 32 F. S. 958 (Petitioner's Opening Brief, pp. 14, 33, 43, 92, 150, 154, 161, 163), despite the Commission's unsupported protests to the contrary in its Brief.

6. The diatribe in the Commission's Brief (Commission's Brief, p. 21) directed against the Petitioner's assertion that Commission's witness, Dr. Carlson, swore *in effect*

that all the various units of the biliary system must be operating normally* in order for the experiments to be valid, is camouflage. Carlson testified (Vol. I, N. R. Carlson 372) that bile acids “play a role in the *emulsification* of the fats in the food, which favors *digestion* of fats, possibly *inactivation of the enzymes in the pancreatic juices, digesting* the fat, possibly in *combining* with the *end products* of fat digestion, in favoring *absorption*.” Carlson was then further asked (Vol. I, N. R. 374 Carlson) “*What are the principal juices*”? And answered (*id.* 374) “Saliva, gastric juice, *bile*, pancreatic juice, succus entericus, or intestinal juice”. In other words, Carlson included *bile* as one of the *principal juices*. Then, under further examination, Dr. Carlson let the cat out of the bag when he admitted (Vol. I, N. R. 375 Carlson) in answer to the question “What about *bile*, in comparison with the *other juices*?”, that bile “is important in the *digestion* and *absorption* of facts, and we don’t do well in the total absence of bile from the intestine, *but one would be fair in saying that all these juices are natural juices, and we are better off if we have all of them, in the average, normal amounts!*”

Obviously, since, as the Commission’s witness, Carlson, was obliged to concede, we are *better off if we have all of these juices, including bile, in the average, normal amounts*, the answer that Carlson gave in response to the question of Petitioner’s counsel (set out p. 21 of the Commission’s Brief) was actually evasive* and susceptible, on the other hand, to the precise interpretation given to it by Petitioner in its Opening Brief (p. 15).

All this Court need therefore do is to take the concession (above noted) of Commission’s witness, Dr. Palmer, of the truth in the main of Petitioner’s advertisement that the liver *should* pour two pints of bile juices a day into the intestines—i.e., that this is the daily required normal output of bile—and add to that concession the further concession of the Commission’s key witness, Dr. Carlson (whom the Commission’s Brief p. 29 calls “one of the greatest physiologists in the world”) *that we are better*

* Vol. II, O. R., *Carlson*, 481-484.

off if we have all these juices, including bile juices, in average, normal amounts, in order for this Court to see at once that the Commission's attempt to have this Court believe the various irresponsible and exaggerated statements of some of the Commission's witnesses to the effect that bile flow can be radically diminished or practically eliminated without harmful results, is, to put it mildly, pure physiological nonsense.

7. By a series of elaborate omissions, the Commission, p. 22 of its Brief, next seeks to create two erroneous impressions, first that its witness, Ivy, satisfactorily explained away *all* the great variety of repeated contradictory statements in his own prior printed publications, made before he performed the experiments in suit, which published statements flatly and squarely—and this Petitioner asserts *truly*—set forth Ivy's really mature and deliberate scientific opinion that there *is* a causal relation between constipation and decreased flow of bile and, second, that there is some kind of impropriety on Petitioner's part either in claiming that Ivy published such views or failed to explain them away. Here, again, the Commission selects for its purpose *some but not all* of Ivy's publications, omitting reference to the others set out in Petitioner's Opening Brief, pp. 69-70* also written by Ivy, in which he made similar public statements of his view that constipation and decreased bile flow are causally inter related.

Again, all that this Court need do, is to read the article by Ivy (which plainly speaks for itself) set out at p. 69 of Petitioner's Opening Brief and its interpretation by Petitioner's witness, Dr. Crandall, set out at p. 78 of Petitioner's Opening Brief and confirmed by Petitioner's witness Dr. McGuigan (Vol. II, N. R. 867-8; Vol. III, N. R. 901-910), in order for this Court to see that the Petitioner is correct both in its interpretation of the article and in its assertion that Ivy never satisfactorily explained it away.

* Through a typographical error Petitioner's Opening Brief, at that point, refers to these other articles as appearing in the testimony of Ivy instead of Bollman. The correct references are (Bollman, Vol. VIII, N. R. 3190, 3202 and 3205).

The Commission (its Brief, p. 22) makes partial quotations from Ivy's so-called explanation of one of his articles dealing with dog experiments. The Commission omits the following vital prefatory part of Ivy's testimony (Ivy Vol. II, O. R., 709) preceding the Commission's quotation, i. e. "That *if you have an adequate flow of bile*, adequate formation of bile by the liver, *being formed in response to good stimulus* then this reflex inhibition of bile—inhibitory influence on bile—is not adequate to stop the formation of bile". What Ivy thus was really saying was in effect (if one paraphrases that statement and applies it to Petitioner's claims) that *if* there is an *adequate* flow of bile (and by necessary supposition there is *not* such a flow of bile in persons for whom Carter's Little Liver Pills are sold i. e. as a laxative "*aiding bile flow*" and "*not for diseases of the liver except those helped by better bile flow*," Commission's Ex. 1A) and that *if*, in addition, you administer a "*good stimulus*" to bile flow (and the ingredients, aloes and podophyllum, in Petitioner's product, as Petitioner has shown, are just that) *then* and only then will the inhibitory effects in decreasing bile flow be overcome.

How palpably unsatisfactory were Ivy's attempts to explain away his prior contradictory published statements will be clear to this Court on reading Ivy's full testimony (Vol. II, O. R., 707-715). As just one example of Ivy's equivocations, on direct examination Ivy said (Ivy, Vol. II, O. R., 705): "You can *divert* the bile from the intestine of dogs and human beings without getting constipation or without constipation occurring" and almost in the next breath, on cross examination, (*id.* 714) "Dr. Ivy, *would a lack of bile contribute to constipation or have a tendency to cause constipation?*", "A. Yes, it would be called a *pre-disposing factor, a complete lack of bile.*"

Entirely unexplained away by Ivy, are Ivy's published statements (Bollman, Vol. VIII, N. R., 3190 that (i) "*Clinical evidence indicates that constipation and bowel spasm contribute to stasis or malfunction of the biliary tract*" and (Bollman Vol. VIII, N. R. 3205) (ii) "Summarizing our data *demonstrate that constipation and sluggish gall*

bladder evacuation *are related*”, and, (iii) that (*id.* Vol. VIII, 3205) “It was *found* that in the case of *both sexes* the *trend toward a correlation between constipation and incomplete gall bladder evacuation was present in all age groups.*” With these latter two statements of Ivy’s, which amply confirm Petitioner’s basic contention as to the causal relationship between constipation and decreased bile flow *in humans*, the Commission’s witness, Bollman (Bollman Vol. VIII, N. R., 3205-6), on remand, *in general agreed!* Suppressed entirely both in the Commission’s Brief and in its Findings also is all reference to the testimony of Petitioner’s witness Dr. McGuigan (Vol. II, N. R., pp. 839-841) supporting the truth of Petitioner’s claim of a causal relationship between constipation and supporting the authoritativeness of the article of Dr. Gauss, and by the same token, Dr. Lichtman, by which latter the Commission’s witness, Dr. Bollman, was in effect discredited (Petitioner’s Opening Brief pp. 70-72; pp. 77-78).*

In Ivy’s published article (Ivy, Vol. II, O. R., 710) concerning certain of his previous *dog* experiments, Ivy wrote:

“The results of these experiments provide two mechanisms by which *constipation* may *promote* gall bladder or biliary tract stasis. *Although they tend to confirm clinical impressions and observations, they cannot be directly applied to men.* They are sufficiently decisive and important to *indicate prophylactic therapy and to stimulate research to ascertain whether such mechanisms actually operate in man.* There is no *a priori* reason to doubt their existence in man.”

These published statements of the Commission’s witness, Ivy demonstrate conclusively the truth of Petitioner’s contentions (Petitioner’s Opening Brief, pp. 25-33), supported by the statements of the Commission’s own witnesses

* See the overwhelming demonstration (ignored by the Commission in its Findings) by Petitioner’s witness, Dr. McGuigan, (Vol. II, N. R. 838-849; 863-869) that “the consensus of the enlightened modern members of the medical profession” supports the *causal relationship* between constipation and bile flow.

and all the other evidence collected at that point in Petitioner's Brief, *that without adequate supplementary experimentation on human beings the Commission's animal tests were not translatable to man.** In fact when this precise same published statement of the Commission's witness, Ivy, was read to the Commission's witness, Bollman, on remand, (Bollman, Vol. VIII, N. R., 3202-3203), Bollman was asked by Petitioner's Counsel "*Did you understand that?*" "*A. Yes.*" "*Q. Do you agree with that?*" "*A. Yes.*".

The evidence overwhelmingly demonstrates (1) that in reality the views of the Commission's own witnesses themselves *actually tend to confirm* Petitioner's basic claim of a causal connection between constipation and decreased bile flow, and likewise tend to confirm Petitioner's assertions of the untranslatability of the Commission's animal experiments to man, and, (2), (Bollman Vol. VIII, N. R., 3179-3206; 3378-3386), at the very *minimum*, present the kind of uncertainty and lack of "general medical agreement"*** which under Point III of Petitioner's Opening Brief is sufficient in itself for the reasons there stated to vitiate the Commission's present order. There was no intention in the Act that the Commission should "become the absolute arbiter of the truth * * *", even where scholars in the particular field of knowledge were in wide disagreement"; *Scientific Mfg. Co. v. F. T. C.*, 124 F. (2) 640, p. 644.

8. There follows here (Commission's Brief, bottom of p. 22 and first paragraph top of p. 23) another series of misstatements by the Commission, the complete answer to

* See the many further authoritative textual statements, in support of this proposition, of Dr. O. H. Horrall (Petitioner's Brief dated November 29, 1955 on Appeal to the Commission, pp. 32-34) recognized as an authority by Commission's witnesses, Carlson (Vol. I, O. R. 466-7; 493; Vol. II, N. R. 450-1) and Bollman (Vol. VIII, N. R. 3227-8).

** See also the testimony of the Commission's own witness, Dr. Palmer, ignored by the Commission in its Findings (Palmer, Vol. II, N. R. 651-653), as to the "difference of medical opinion" on certain conditions improved by better bile flow, and, it seems, a great deal of difference of opinion on various issues involving the biliary system, full cross examination as to which was blocked by the Commission's Examiner (Palmer, Vol. II, N. R. 653).

which, with supporting record references has already been furnished at pp. 24-25, 39-40 and 137-139 of Petitioner's Opening Brief. There in detail the truth is made clear of Petitioner's assertions that the Commission's witness Ivy's own testimony, actions and procedures demonstrated, out of his own mouth, that reliable quantitative results are actually obtainable by the use of the duodenal drainage method employed by Petitioner's witnesses which method was erroneously discredited by the Commission through its bias and prejudgment of this case. To the arguments and record references squarely supporting the validity of the duodenal drainage method used by Petitioner's witnesses set out at that point in Petitioner's Opening Brief, should also be added the testimony of the Commission's witness, Ivy, (O. R., Vol. IV, pp. 1536-1537, Ivy) that such method "is always reliable when you use a potent stimulant", which is precisely what Petitioner claims, and the record shows, aloes and podophyllum are. *And, of course, there should also be added the wealth of scientific authority supporting that method, as to which Bollman was not cross examined, but which was timely offered by Petitioner and rejected by the Examiner while the proceedings were still pending before him, in which rejection he was sustained by the Commission on appeal.* Because space does not permit of adequate presentation here, the Court is earnestly requested to read the discussion of the Commission's and the Examiner's reversible error in rejecting in this respect this Offer of Proof at pps. 16-19 of Petitioner's Brief (dated Nov. 29, 1955) on Appeal to the Commission and pps. 7-8 of Petitioner's Supplemental Brief (dated May 11, 1956) on Appeal to the Commission. These Briefs are a part of the record certified to this Court, extra copies of which have been furnished to it.

9. Next, p. 23 of the Commission's Brief, the Commission makes the completely unfounded charge that "Perhaps one of the worst examples of distortion indulged in by petitioner in its brief appears on page 150 * * *", concerning Bollman's testimony.

If the Court will carefully examine the Petitioner's statements at pp. 149-150 of its Opening Brief, and the

full context of Bollman's testimony commencing p. 2569 and ending p. 2577, Vol. VI, N. R., and, Bollman's testimony, bottom of p. 1495 through 1496, Vol. IV, O. R., three things will be apparent to the Court: (1) the correctness of Petitioner's interpretation of Bollman's testimony or writings and those of other witnesses concerning the lack of sufficient sensitivity of liver function tests in general, either as an adequate measure of normal bile function, or as a means of accurately gauging or assaying increases in bile flow such as are produced by Petitioner's product or by other accepted products commercially used to increase the flow of bile, (2) the correctness of Petitioner's interpretation of the testimony of Bollman, and (3) the lack of justification for the Commission's unwarranted assault on Petitioner's statements.

This Court will incidentally glean from an examination of this testimony of Bollman's (N. R., Vol. VI, pp. 2569 through 2577) two other things, first, a typical example (though comparatively mild) of which there are literally hundreds of others in this vast 11,000 page record, of the kind of harassing and thwarting tactics of the Commission's Counsel* which beset Petitioner in the conduct of its defense at every step throughout this entire litigation and, second, further confirmation (see Petitioner's Opening Brief, pp. 98-99) of the fantastic farce of Bollman's *gross* post-mortem inspection of the livers of his three dogs "after", as this Court said in its prior opinion in this case, 201 F. (2) 446 at p. 450, "varying degrees of post-mortem degeneration had taken place." Bollman made nothing but a *gross* examination—and not, of course, a microscopic one—and Bollman conceded (Bollman, N. R., Vol. VI, pp. 2576-7) that "at other times I would not be able to, or

* Eloquent evidence of the lengths to which Commission's Counsel went in hindering effective cross examination by Petitioner of the Commission's witnesses after the remand, is provided by the fact that even the Examiner himself rebuked Commission's Counsel for such tactics (Vol. VIII, N. R. p. 3291) and repeated that rebuke in his Supplementary Report (Vol. I, N. R. p. 194), saying " * * * I have had to fight that very thing at almost every step of this proceeding since it has been reopened, because of your objections, and very frankly, Mr. Cohn, if I may use that colloquialism, I am getting fed up on it."

having drawn such conclusions from the *gross* examination *I would change them on the microscopic examination*, but I might be mistaken, because I say, you can only see what you can see". Bollman likewise confessed (*id.* pp. 2576-2577) that he had previously published an article, which he endorsed as still correct in which he gave it as his view that "The *gross* appearance of the liver, while useful in classifying livers as normal, chronically inflamed or definitely cirrhotic, *did not give accurate information with regard to the degree of physiologic change which was associated with the pathological findings.*"

No further comment is necessary.

10. Next (Commission's Brief, pp. 28-29) under the heading "Petitioner's Laxative Pill Will Have No Effect Upon the Formation or Flow of Bile", the Commission, as a kind of last resort, appeals generally to the alleged eminence of its expert witnesses, ignoring the obvious fact that eminence and reputation are neither substitutes for proof nor guarantees against bias, for, as the Court held, in *Chandler v. Mock*, 150 F. (2) 563 p. 567, an expert's "reputation cannot be utilized to cover a deficiency in evidence."

11. Next (Commission's Brief, pp. 30-33) comes a discussion by the Commission entitled "Experiments Performed by Dr. Ivy To Determine If Petitioner's Laxative Pill Will Have Any Effect Upon The *Formation* of Bile by The Liver".

There is here no attempt to answer the irrefutable evidence emanating from the Commission's own witnesses (ignored by the Commission through its bias and prejudgment of the issues in this case) which, on the face of things and self-evidently, invalidated these experiments (Petitioner's Opening Brief, pp. 13-44). Neither is there here any attempt to justify the plain denial of due process committed by the Commission through its Examiner (Petitioner's Opening Brief, pp. 18-19) in foreclosing proper cross examination of the Commission's witness, Ivy, by Petitioner in order to demonstrate through him that by his addition, for six whole days, of enormous extra doses of

of artificial bile salts, the test animals, on Ivy's virtual admissions, had already reached the peak of their ability to put out any further bile in response to the administration, on top of these bile salt, of doses of Petitioner's product.*

Further the Commission fails here to point out to the Court that the experiments here discussed, which dealt with the *formation of bile* by the liver, were, of course, as a further condemnation of them, *totally irresponsive* to Petitioner's basic claim that its product is "a laxative aiding bile flow", "not for diseases of the liver except those helped by a better *bile flow*" (Commission's Ex. 1-A). Such experiments were therefore utterly inapposite to Petitioner's claim of the *cholagogic* effect of its product. A cholagogue is a substance (Examiner's Report, O. R., Vol. I, p. 80) "which increases the *flow of bile into the intestine*, as, for example, by facilitating gall bladder evacuation", while, on the other hand, (Examiner's Report, *id.*) a "*Choleretic* is a substance which increases the *formation of bile by the liver.*" Again no further comment is necessary.

12. The Commission (its Brief, bottom p. 33) quotes Petitioner's witness, Dr. Crandall, as testifying "that he did not think constipation under any circumstances decreased the flow of bile to such an extent as to *affect* the digestive process". The record contains no such testimony, and this plain misconstruction further omits to quote Dr. Crandall's testimony (Vol. VII, N. R., 2919):

"Q. Doctor, is it your opinion that functional constipation in any form *injures* the liver insofar as its secretion of bile is concerned? A. I have no *fixed* opinion on that subject, *but I am inclined to believe what you say possible.*" * * * "That is to say, I think it is *entirely reasonable on the basis of the evidence we have to think that functional constipation may decrease the flow of bile.*"

* Denial of this basic constitutional right of cross examination of Ivy on this material and vital issue is both reversible error and a denial of due process; *Alford v. U. S.*, 282 U. S. 687, pp. 691-2. "Cross examination of a witness is a matter of right, * * * It is the essence of a fair trial * * *". *Reilly v. Pinkus*, 338 U. S. 269, pp. 275, 276.

Commission's Counsel himself read into the record (Crandall, *id.*, 2919) Dr. Crandall's published statement that "Fat absorption is then not *entirely* dependent on the presence of bile, *but must be greatly facilitated by bile salts* since I have found and have previously reported to this Society that a fat meal does not cause the *usual* increase in blood fat when given to the *bile fistula dog*"—in other words, where (as before explained in this Brief), the bile is diverted from the dog's intestines, as, for example, in Ivy's dog fistula experiments. Also, similarly read into the record (Crandall, *id.* 2918) was another published statement by Dr. Crandall to the effect that although the human bile salts "are not *essential* for the splitting of fat to fatty acids and glycerol by the lipases of the pancreatic juice and intestinal secretion", "*they unquestionably accelerate* that process." Obviously, in view of this testimony and these published statements of Petitioner's witness, Dr. Crandall, and the testimony of the Commission's witness, Dr. Carlson (*supra*) to the effect that "we are better off if we have *all* the natural juices (including bile salts) *in average normal* amounts", it follows as a matter of common sense that decreasing those juices below normal *affects* the normal functioning of bile salts and *affects* the normal functioning of the digestive system. That it does not actually *prevent altogether* the functioning of bile (Crandall Vol. IV, O. R., 1672) is obviously quite a different matter.

13. The discussions in the Commission's Brief, pp. 34-54, under the respective headings "Experiments Conducted by *Dr. Ivy* to Determine If Constipation Affects The *Flow* of Bile", "Experiments Conducted by *Dr. Bollman* To Determine If Constipation Affects The *Flow* of Bile", "Experiments Conducted by *Dr. Ivy* to Determine If Petitioner's Laxative Pill Will Have *Any Effect Upon The Gall Bladder*", "Experiments Conducted by *Dr. Case* To Determine If Petitioner's Laxative Pill Will Have Any Effect *Upon The Gall Bladder*" and "Petitioner's Laxative Pill Will Not Affect The *Flow of Bile* In Any Manner" simply make no serious attempt (in fact the Commission's Brief abandons any attempt whatsoever) to answer either the

specific, detailed, irrefutable showing of the hopeless, self-apparent vices in the Commission's experiments disclosed in Petitioner's Opening Brief pp. 10-44 and 66-105 or the violations of due process in connection therewith which the Commission committed throughout this case either itself or through its Examiner.

A footnote, p. 36 of the Commission's Brief, attempts to answer Petitioner's clearly justified objection to Bollman's bizarre dog tests as being further *totally unrepresentative* because they were performed on *only 3 dogs*. The Commission's statements there ignore the very same type of objection on Ivy's own part (Petitioner's Opening Brief, p. 100) i. e., that animal tests require "the performance of a *number of tests either on the same or on a group of different animals.*" The footnote also omits to state that the Commission's own witness, Dr. Carlson, voiced the same view as to the lack of the sufficiently representative character of tests performed on animals when he wrote in his book, "The Machinery Of The Body", regarding the danger of generalization of animal tests with drugs, "Perhaps by accident the *few dogs* employed were *not representative* of dogs in general"—another of the important authoritative scientific writings (in fact an admission by the witness himself) contained in Petitioner's Offer of Proof and erroneously excluded by both Examiner and Commission (See Vol. I, N. R. pp. 42-43 for full reference and quotation). For just such a cogent reason i. e., lack of a sufficiently representative character, Judge Woolsey condemned the government's tests as without "juridical effect" in *U. S. v. 59 Tubes etc.*, 32 F. S. 958, namely because of the untenable assumption "that the test animals are all substantially identic in their reaction, metabolism" p. 962.

As to the italicised portion of the statement by the Commission (p. 46 of its Brief) that "*After the effect of the above experiments on the dogs had worn off*, a second series of experiments were performed", no record reference supports this statement. It further appears that the animals were under the effects of anaesthesia (Ivy II O. R. 627, 630, 642 and Vol. II, N. R. 700). As to the short term experi-

ments, Ivy answered (Vol. II, N. R. Ivy 700) "In Exhibit 98, all of the animals were anesthetized." "Q. *All the time during the course of the experiment?*" "A. Yes."

By way of further illustration of the kind of misstatement in which the Commission in its Brief (at this point and elsewhere) indulges, is the Commission's statement concerning Bollman (having reference to the unsavory incident in which Bollman attempted to discredit the method employed by Petitioner's witness, Dr. Morrison, and was caught in an untruth on cross-examination after remand) that Bollman (Commission's Brief, p. 38) "*himself did not make the statistical determination*". This Court is invited to read Bollman's testimony (p. 88 Petitioner's Opening Brief) concluding with the following question and answer by Bollman, showing the error of the Commission's statement in its Brief:

"Q. You did *not* do the statistical analysis of Morrison data, but *you did do* the statistical analysis of *your own data* as set forth in three exhibits I have just mentioned? A. *That is correct.*" (Bollman, Vol. VIII, N. R. pp. 3365-6).

Despite the especially heavy affirmative burden of proof which the circumstances imposed upon the Commission in this case, none of its witnesses were professional statisticians and the Commission made no proper offer of proof by statistical experts of the statistical significance of its experiments. Dr. Ivy testified "I am not an expert in the field" (Vol. VII, N. R., Ivy, p. 2773). And yet, in demonstration of the necessity of statistical evaluation, the Commission's witness, Dr. Carlson, wrote, ("Machinery Of the Body") "Special mathematical techniques employed in statistics may be required to determine whether the difference observed in the experimental and controlled groups are probably significant or probably due to chance"—another authoritative scientific textual statement—again by a witness for the Commission—which the Examiner and the Commission wrongfully excluded (Vol. I, N. R., p. 45). This

vital insufficiency in the Commission's experimental proof is confirmed by the testimony of the Commission's witness. Dr. Bollman when on the original hearings he said that after certain preliminaries " * * * I usually ask a statistician to determine the *significance* of the data which I supply him with *on a statistical basis*" (Vol. IV, O. R., Bollman p. 1486.)

14. The Commission's discussion (its Brief pp. 54-56) of the testimony and experiments of Petitioner's key witness, Dr. Killian, conveniently omits all reference to the following facts (Petitioner's Opening Brief, pp. 107-112) (a) that at the precise and crucial point where this witness for Petitioner was endeavoring to *explain*, supplement and interpret his experiments by legitimately expressing his expert opinion that Petitioner's product had the effect of increasing bile flow *not confined to the four conditions of his experiments*, he was abruptly blocked and shut off from completing the record on this point by the act of the Commission through its Examiner. *This was a flat denial on its part of constitutional due process** to Petitioner and was made even more damaging and discriminatory by the fact—again omitted from the Commission's Brief—that the Commission through its Examiner (Petitioner's Opening Brief, pp. 112-113), with characteristic bias, compelled Petitioner's witness, Dr. Hazelton, on the other hand, to render opinions outside the scope of his experiments; (b) by the fact that the validity of Killian's experiments is fully documented and sustained at pages 66 through 120 of Petitioner's printed Brief dated February 1, 1947, filed with the Commission at the close of the original hearing, a printed copy of which is included in the record certified to this Court (to which the Court is respectfully referred) and (c) by the fact that there is no express Finding by the Commission that Petitioner's experimental proof including Killian's

* *Throckmorton v. Holt*, 180 U. S. 552, p. 565; *Int. Com. Commission v. Louisville & Nashville R. R. Co.*, 227 U. S. 88, p. 93, *supra*, holding that the right to offer evidence in "explanation" is a constitutional right.

does not constitute substantial evidence. The Commission made only the erroneous and wrongful finding applied to Petitioner's proof alone, i.e., that it is not "conclusive", by which (as Petitioner has demonstrated in its opening Brief, pp. 9, 40, 41, 114, 115, 116-121, and the Commission in its Brief makes no attempt to specifically deny) Petitioner was effectively deprived of its day in court and denied due process of law.

15. At pages 56-57 of its Brief the Commission resorts to a series of distortions of the whole purpose and intent of the testimony and experiments of the Petitioner's witness, Dr. Hazelton, which is proof positive of the Commission's bias and fixed closure of mind, culminating with the misleading statement (Commission's Brief, pp. 56-57) that "Since in his experiments Dr. Hazelton injected aloes and podophyllum *intravenously* into the dogs and in the experiments conducted by the Commission's witnesses these drugs were injected into the duodenum of the dogs, *the experiments are totally different*".

The misleading nature of this statement is demonstrated by (1) Ivy's statement in Commission's Ex. 98 (reproduced in full at p. 563, Vol. II, O. R., Ivy) being the Commission's witness, Ivy's, account of his own experiments, that "In this report we shall present the results obtained when the ingredients of Carter's Little Liver Pills were given *intravenously* or intraduodenally," (2) by the Commission's witness, Ivy's own testimony (Vol. IV, O. R., Ivy p. 630) that "we would inject a suitable solution of Carter's Little Liver Pills *intravenously* and then wait for another half hour or two hours", (3) by the statements with regard to Ivy's experiments in the Commission's Brief itself (p. 45) "six of petitioner's laxative pills were ground and dissolved in alcohol, diluted with water and injected *intravenously* twelve times in seven days" and again as to the experiments of its witness, Ivy, (Commission's Brief p. 46) "After one and one-half to two hours, 2 of petitioner's laxative pills were dissolved in a solution of alcohol and water and injected slowly *intravenously* into the dogs

and finally, of course, (4) by the fact that Dr. Hazelton's experiments involved also administration of aloes and podophyllum duodenally as did Ivy's (Examiner's Original Report, Vol. I, p. 225, and Hazelton N. R., Vol. II, pp. 73, 748, 749, Petitioner's Ex. 14).

Proof of the futility of the Commission's further denials (Commission's Brief pp. 56-58) of the materiality and relevance of Dr. Hazelton's experiments are, among other things, the strenuous efforts (Hazelton; N. R., Vol. II, 729, 741-746) which the Commission's Counsel made on the hearing to exclude the testimony of Dr. Hazelton explaining their effect and purpose, namely to prove the truth of the assertions made at pp. 34-39 of Petitioner's Opening Brief that Ivy's short term dog experiments (Commission's Ex. 98, O. R., Vol. I, p. 563) undertaken to show that Carter's Little Liver Pills do not increase the flow of bile were worthless because the tests were not prolonged for a sufficient period of time to allow the delayed action of the drugs, aloes and podophyllum, (8 to 12 hours as Ivy testified) to take effect.*

That the Commission's Examiner well understood the relevance and materiality of Dr. Hazelton's assault, through his experiments and testimony, upon Ivy appears clearly (Hazelton, Vol. II, N. R., 728-729):

"Mr. Hanaway: * * * I am going to argue later on in the case that this method in certain respects was identical with the method used by Dr. Ivy. I think I am entitled to ask this expert why it was that the results that he obtained on these six dogs were inconclusive. It goes directly to the issue in the case."

"Trial Examiner Purcell: Are you attempting to get your own witness to say that the experiments which he conducted, now introduced in evidence, are inconclusive?"

* See the uncontradicted testimony of Petitioner's witness, Dr. McGuigan, also ignored by the Commission (Vol. III, N. R., p. 896), confirming the length of time required for the action of these drugs, and the testimony of Dr. McGuigan, similarly ignored (Vol. II, N. R. 852 and Vol. II, O. R. 925-27), conclusively exposing the fallaciousness of Ivy's experiments.

“Mr. Hanaway: No. I am trying to establish that this method for determining bile flow is *not a sufficiently sensitive method.*”

Precisely, in other words, what the Commission, in its Brief, as shown above, has unwarrantably taken Petitioner to task for claiming to have demonstrated in its Opening Brief, namely *that the methods and liver function tests employed by the Commission's expert witnesses were not sufficiently refined for their purposes.*

Then, after objections by the Commission's Counsel, preliminarily sustained by its Examiner (*id.* 728, 729) and further objections from Commission's Counsel (*id.* 737, 738) again preliminarily sustained by its Examiner (*id.* 741-746), the Petitioner's witness, Dr. Hazelton, was finally permitted to answer (*id.* 746-747) that “following intravenous administration the total stimulant action of aloes is not complete within two hours”, and after still further objections by the Commission's Counsel (*id.* 747) Dr. Hazelton was allowed to answer that (*id.* 748) “It is a fundamental pharmacological principle that the intravenous route of administration produces results more rapidly than the oral or the comparable duodenal administration, and since in our tube experiments, as has been brought out, we did not carry our period of observation beyond two hours, I feel that we could not have possibly made those tube experiments valid.”

“Trial Examiner Purcell: I see.

“The Witness: Even after *intravenous* injection it takes two hours and that is as long as we ran those experiments” (*id.* 748).

Subsequently the Trial Examiner commented (*id.* 749-750):

“The witness now says that the allotted time is incomplete *both duodenally and intravenously*”.

“Mr. Hanaway: He did not say that.” * * * He said that the period that he allotted for the collection of the bile in the tube, t-u-b-e dogs was not long enough, that two hours was not long enough to allow the full and complete action of these drugs.”

“Trial Examiner Purcell: In other words, to form a full evaluation of the action of the drugs, is that right?”

“Mr. Hanaway: That is right, and if you will recall Dr. Ivy’s experiments were on periods of time in one case in Exhibit 98 I think they were for as short as one hour. His periods of observation were as short as one hour.” * * *

“Confirming my remarks now to the tube dogs, all they show is that the two hour period was insufficient; so far as the intravenous dogs are concerned those experiments are complete.” * * * “*It indicates that Dr. Ivy’s work was incomplete, and that is what I am putting it in for.*” * * * “not for the purpose to show that *this man’s** work was incomplete but to demonstrate that *Dr. Ivy’s work is incomplete*. I think I am allowed to do that.” (*id.* 750).

The Commission through its Counsel then renewed its objections and also moved to strike Dr. Hazelton’s answers but was overruled by the Examiner (*id.* 750-752) who, however, along with the Commission, gave neither effect nor proper consideration to their destructive impact and the destructive impact of Hazelton’s experiments on the Commission’s witness, Ivy’s, experiments. The Commission’s whole distorted treatment in its Brief, pp. 56-58 of Dr. Hazelton’s experiments and evidence demonstrates that the Commission even now persists not only in ignoring but in positively distorting the purpose and effect of Dr. Hazelton’s experiments and testimony — namely to demolish Ivy’s. It is no wonder that the Commission also erroneously ignored the forceful testimony of Petitioner’s witness, Dr. McGuigan, exposing the “absurdity” of Ivy’s protocols (McGuigan, Vol. II, O. R. 924-927) ending with his denunciation of Ivy’s Paper (Commission’s Ex. 97). “Q. Is there anything else wrong? A. There is a whole lot in the thing. The paper is so full of errors in computation it is just the worst paper I have ever seen published, as far as errors go.

* *i. e.* Dr. Hazelton’s.

There are more errors in that paper, I think, than any paper I have ever seen published. Lieutenant Annegers says those are typographical errors. They are not. They are changed figures. I recognized them.”

16. Next (Commission’s Brief p. 57), although it has been repeatedly pointed out to it by Petitioner’s former Briefs that its own witnesses pursued the same practices,* the Commission makes further demonstration of its persistent bias in its credibility evaluations of its own and the Petitioner’s witnesses by again repeating its discrediting of Petitioner’s witness, Dr. Morrison, because he did not tell his experimentees that they were receiving “administration of petitioner’s laxative pills”, etc., etc. Of course, characteristically the Commission took no note in its decision of the condemnation of Ivy’s paper (Commission’s Ex. 97) by the Petitioner’s witness, Dr. McGuigan, (Vol. II, O. R. 924-927), “There are more errors in that paper, I think, than any paper I have ever seen published. Lieutenant Annegers says those are typographical errors. They are not. *They are changed figures. I recognized them.*” No further comment is necessary.

17. Finally the assertions by the Commission in its Brief (pp. 58-64) under the heading “Petitioner Was Not Denied A Fair and Impartial Hearing”, and the Commission’s insinuations that Petitioner should have moved before to disqualify the Examiner, amount to precisely nothing.

In view of the severe castigation by this Court in its prior opinion of the Commission’s Examiner’s tactics (which tactics the Commission had previously approved despite Petitioner’s protests in its original Brief filed with the Commission at the close of the hearings and which tactics the Commission still approves) which were held by this Court to amount in effect to a complete

* See also Petitioner’s Opening Brief p. 47 last paragraph and pp. 48-49 showing that Commission’s witness, Dr. Case, pursued, without any criticism whatsoever on the Commission’s part, similar practices.

denial to Petitioner of due process and “*to deprive petitioner of a fair hearing*”, it is obvious that, in fairness to the Commission, Petitioner was entitled to assume that both the Commission and its Examiner would heed this Court’s admonishments, amend their ways and dutifully proceed to correct the mispractices which this Court held to have deprived this Petitioner of its constitutional right to a fair hearing, and to refrain from a repetition of such practices. Petitioner was entitled also to persist in its belief (though it later proved to be a fond one) that the Commission’s Examiner would not again turn a deaf ear to the spirit and purpose of this Court’s opinion and mandate, and Petitioner was fully justified in so doing up to the very last when the Examiner’s pent up animus and bias finally burst into the clearest light of day* in the extravagant and false series of charges of abuse of process by Petitioner and its Counsel and all of the Examiner’s other venomous insinuations and false innuendoes, including his belittling of the basis of Petitioner’s former highly necessary and justified appeal to this Court and of this Court’s holding sustaining that appeal, fully revealed for the first time in the Examiner’s Rulings and Supplementary Report (Petitioner’s Opening Brief, pp. 122-133).

Nowhere in the Commission’s Brief does it make either any attempt or demonstration—as of course it cannot—to overcome the overwhelming proof contained in this Reply Brief and in the Opening Brief of Petitioner, that its Examiner (and for that matter the Commission itself) was plainly and prejudicially biased.** The Commission contents itself with the lame statement (Commission’s Brief p. 60) “that any bias and prejudice of the examiner

* On the vitiating effects of bias first clearly appearing during trial, *Whitaker v. McLean*, 118 F. (2) 596; *Knapp v. Kinsey*, 232 F. (2) 458; *Knapp v. Kinsey*, 235 F. (2) 129 and cases cited in Petitioner’s Brief on its Motion to Disqualify the Examiner, dated April 25, 1955 at pps. 3-6, which is a part of the Record filed in this case.

** And of the demonstration of the consequent futility of introduction in evidence by Petitioner before such an Examiner of the new Twiss experiments performed since the original hearings (Petitioner’s Opening Brief, pp. 134-145).

which may have existed cannot form a basis for a determination that petitioner was denied a fair and impartial trial *unless* the Examiner committed some *act* either in refusing to admit testimony, exhibits or in restricting the rights of petitioner in some manner resulting in prejudicial error''. This statement complacently ignores, and fails to answer, the overwhelming proof of *just* such acts on the Examiner's and on the Commission's own part demonstrated from this very record, (including restrictions on the Petitioner's constitutional rights of cross examination and rebuttal) in Petitioner's Opening Brief and in this Reply Brief condemned as prejudicial error by the Supreme Court in *Alford v. U. S.*, 282 U. S. 687, pp. 291-2, and *Int. Com. Commission v. Louisville & Nashville R. R.*, 227 U. S. 88, p. 93.

18. Added to that detailed demonstration, is the following further proof that in adhering to its Examiner's Reports and Recommendations, the Commission was also further misled into making various Findings because of the Examiner's misstatements of the evidence contained in his Original Report.

In this Report the Examiner indulged in the misleading practice of creating the false impression in the Commission's mind that examination of Petitioner's own witnesses disclosed damaging admissions by them. As a typical instance (Vol. I, O. R., p. 215, Examiner's Original Report) in the Examiner's zeal to discredit Petitioner's witness Dr Killian's experiments in a point vital to Petitioner's case (which in the Commission's eyes, at least, he appears to have succeeded in doing) the Examiner reports in criticism of Dr. Killian,

"373. *On further examination of the witness [i.e. Killian] concerning the last hereinabove set forth conditions for increase of the bile flow, it developed:*

"374. That the administration of the pills will not increase bile flow in the duodenum when given in adequate doses over a sufficient period of time to produce laxation as set forth in Condition 1 above, (Tr. 9591-92, 9525-26)".

These Transcript references, as the Court will see by examining the printed record where these references to the Transcript occur (O. R., Vol. IV, pp. 1553-4, *Ivy*, and O. R. *id.* 1533; N. R., Vol. VII *Ivy* pp. 2738-9) are *not* to the examination of Petitioner's witness, *Dr. Killian*, at all *but*, on the contrary, to the testimony and examination of the Commission's witness, *Dr. Ivy*. At other times, a variant of these misleading practices of the Commission's Examiner was to put the words of the Commission's witnesses into the mouths of witnesses for the Petitioner with the object again of creating the false impression in the Commission's mind that Petitioner's witnesses were themselves making damaging admissions. For example (Vol. I, O. R., Examiner's Original Report p. 205), and again as to Petitioner's witness, *Dr. Killian*, the Examiner reports, "Witness (i. e. *Killian*) testified that even had the administration of Carter's Little Liver Pills under the conditions of his experiments produced an increase in the flow of bile, such increase would serve no utilitarian purpose (Tr. 7828, 9097, 9602-9603)". Again, as this Court may see from examining (N. R., Vol. V, p. 2224 and N. R., Vol. VI, p. 2225) where the first of these references to the Transcript occur, there is no such statement by *Dr. Killian*; and if the Court examines O. R., Vol. IV, p. 1432, *Bollman*, and N. R., Vol. VII, pp. 2768-9, *Ivy*, where the next two references to the Transcript occur, the Court will see that the *one* is to testimony of Commission's witness *Dr. Bollman* (and *not* to *Killian*) having nothing to do with the subject, and that the other is to the Commission's witness *Ivy's* testimony (and *not* *Killian's* testimony) agreeing in part and disagreeing in part with *Dr. Killian's* testimony.

Still more prejudicial to Petitioner is this further variant of the Examiner's misleading practices in his Report—prejudicial because it was intended to, and doubtless did accomplish the result of misleading the Commission into a distrust of the thoroughness and adequacy of the experimental protocols of *Dr. Morrison*. The Examiner (O. R., Vol. I, Examiner's Report pp. 147-8), under the heading "Cross examination of *Dr. Morrison* developed the fol-

lowing testimony'', finds in effect that the cross examination of Dr. Morrison revealed defects in his protocol because of the administration *concomitantly* with aloes and podophyllum of another biliary stimulant, magnesium sulphate, so that, as the Examiner there concludes (*id.* pp. 147-148):

“* * * Morrison made no attempt to determine, when the drainage was collected following the administration of magnesium sulphate, whether or not that drainage was affected by the aloes and podophyllin, and vice-versa, where the aloes and podophyllin were first administered followed by magnesium sulphate, no attempt was made to determine whether or not any effect remained from the previous injection.”

In other words the Examiner reports in Morrison's case *only as fatal to Morrison's protocol alone** precisely the same type of fatal objection to Ivy's and Case's protocols which Petitioner makes in its Opening Brief—namely, the very same type of use by these witnesses for the Commission of bile salts, cholecystokinin and the fatty meal and all the other cumulative stimulants and upsetting variables from whose concomitant and combined use it was impossible to tell what effects were due to the aloes and podophyllum or to these other stimulants or to both.

19. The misleading statements in the Commission's Brief (pp. 61-2) which seek to make it appear to this Court that because Petitioner was permitted to cross examine Commission's witness, Bollman, as to *certain* contradictory textual authorities (though both the Commission and the Examiner ignored completely all effects of such cross examination and of such contradictory authorities)—no prejudicial harm was done, *omit* all reference to the all essential and important circumstance of the complete rejection and disregard by both Examiner and the Commission, which sustained that rejection, *of all the many other additional*

* No mention of these same objections is made by the Examiner in his Report concerning Ivy's and Case's experiments (*id.* 93-117).

scientific texts and authorities also flatly contradicting the testimony of the Commission's witnesses *on vital areas* of Petitioner's case. Some of these are discussed above in Reply Brief. All of them and the detailed legal reasons and authorities for their admission and consideration by the Commission were urged upon the Commission in Petitioner's Appeal Brief dated November 29, 1955 (copies of which have been supplied to the Court) at pp. 16-19; 26; 32-34 and at pp. 7-8 of *Petitioner's Supplemental Brief on Appeal to the Commission, dated May 11, 1956*, which is likewise a part of the record filed with this Court.* With respect to *these other* rejected and important Exhibits whose existence was first discovered, and which were rejected, while the proceedings were still pending—Bollman was *not* cross-examined. Because of the importance of these issues (and Petitioner's inability for space considerations to treat them adequately here) the Court is respectfully urged to read the full statements (above referred to) in Petitioner's Brief and Supplemental Brief on Appeal to the Commission. These rejected offers of proof emanating from eminent medical authorities, most of whom were never recognized as authoritative by the Commission's decision, Bollman or otherwise properly established as authoritative, related (among other basic issues), to the important issue in this case of the validity of Petitioner's witnesses' use of the duodenal drainage method, and the admission and consideration of these authorities were consequently essential to Petitioner's basic rights.

To these legal authorities demonstrating the Commission's error in failing to receive in evidence or take official notice of these medical texts offered by Petitioner and rejected by the Commission, should be added the following authorities demonstrating that without further proof or other authentication the Commission *should* have received

* See also Petitioner's Opening Brief, p. 30, and Federal Administrative Procedure Act (5 U. S. C. 1006(d)). Commission's Counsel made no request to disprove these matters of which the Commission and the Examiner were requested to take notice.

and considered them and that this Court *can*, itself, consider them on the present appeal:

On this very issue of “*consensus of medical opinion*”, the Court in *Kelly v. Maryland Casualty Co.*, 45 F. (2) 782, pp. 784-5, on its own initiative consulted dozens of medical textbooks which had neither been authenticated, offered nor introduced in evidence, in order to determine this same issue. In fact the Court held p. 784 “*It is the duty of a judge in my situation to inform himself as well as he reasonably may concerning the reasons for differing medical opinions before he undertakes to make choice between them.*” Here the Commission deliberately made arbitrary choice between two differing sets of general medical opinion on the two key issues of this case, i.e., the reliability of duodenal drainages and the relationship between bile flow and constipation, without even considering the differing opinions contained either in the contradictory medical texts with respect to which Bollman was actually re-cross-examined or in those which were included in Petitioner’s Offers of Proof and rejected by the Commission. On the other hand Judge Clark in *Belmont Laboratories v. Federal Trade Commission*, 103 F. (2) 538 p. 539 himself consulted innumerable such texts not authenticated and not offered in evidence and based his decision thereon in a similar proceeding. So did the Supreme Court in *Jacobson v. Massachusetts*, 197 U. S. 11 and *Brown v. Board of Education*, 347 U. S. 483. In *Application of Norris*, 179 F. (2) 970, the Court acceded to a request in counsel’s brief to take judicial notice of two text books on organic chemistry—an inductive science—and quoted extensively from these texts in support of its opinion. See also to the same general effect *Washington State Apple Advertising Commission v. Federal Security Administrator*, 156 F. (2) 589 (9th Circ.) *Beach v. Beach*, 114 F. (2) 479; *Canadian-American Pharmaceutical Co. v. Coe*, 126 F. (2) 847, and *Durham v. U. S.*, 214 F. (2) 862, in which the Courts themselves cited, used and took note of plaintiff’s texts not introduced in evidence, and this Court’s opinion in *Willapoint Oysters v. Ewing*, 174 F. (2) 676, p. 689, in which in a footnote this Court cited

textbook to show that the government's organoleptic examinations were "less efficiently conducted and with less scrupulous regard to scientific media."

It is elementary that "The Court may inform itself in books of authority, though not introduced in evidence, may admit such works to aid it in the exercise of its judicial function"; *In re Siemen's Estate* (Sup. Ct., Pa.), 189 A. (2) 280, p. 282, cert. den. 320 U. S. 758. *A fortiori* this is true of administrative agencies which are not bound by technical rules of evidence. In *Nicotra v. Bigelow Sanitary Carpet Co.* (Sup. Ct. of Errors of Conn.), 189 A. 603, the Court said p. 606 "respondent claims that it was error for the Commissioner to receive the statement from a medical authority (i.e., Encyclopedia of Ophthalmology) over the claim that such statements are inadmissible. This claim overlooks the nature of the hearing before the Commissioner. On such a hearing, great latitude is permitted to the Commissioner in the admission of evidence";* compare Professor Kenneth Culp Davis "Evidence in the Administrative Process", 55 H. L. R. p. 419, and State Court decisions from some eighteen jurisdictions collected in *Wigmore on Evidence*, 3rd Ed., Vol. 6, Section 10, p. 21, in which courts themselves uniformly take judicial notice of scientific matters and cite and consult textbooks (not introduced in evidence) as bases for their opinions. See *Chiulla DeLuca v. Board of Park Comm'rs* (Sup. Ct. of Errors, Conn.), 107 A. 611; *State Board of Medical Examiners v. Plager* (Sup. Ct. N. J.), 193 A. 698; *Peo. v. Jennings* (Sup. Ct. Ill.), 96 N. E. 1077, p. 1081. Further recent decisions are *McKay v. State* (Texas), 235 S. W. (2) 173; *People v. Bobczyk* (Ill.), 99 N. E., (2) 315; *State v. D'Antonio* (Sup. Ct. N. J.), 115 A. (2) 371; *In re Mundy* (Sup. Ct. N. H.), 85 A. (2) 371; *Bailey v. American General Insurance Co.* (Sup. Ct. Tex.), 189 S. W. (2) 315, p. 321; *Loftin v. Yancey* (Sup. Ct. Okla.), 189 P. (2) 107; *Boshers v. Payne* (Sup. Ct., Idaho), 70 P. (2)

* Authorities cited pps. 17-19 Petitioner's Brief in Appeal to the Commission.

391, p. 395; *Guarantee Ins. Co. v. Industrial Acc. Commission* (Col. Dist. Ct. Appeal), 199 P. (2) 12; *Frank v. Atlanta Life Ins. Co.* (St. Louis Court of Appeals, Mo.), 211 S. W. (2) 940; *State v. Goettina*, 158 P. (2) 865, p. 877 (Sup. Ct. Wyoming); *Kennedy v. Parrott* (Sup. Ct., North Carolina), 90 S. E. (2) 754, p. 756. "It would make for greater expedition and for fuller utilization of administrative skills and knowledge if there were more liberality in respect of official notice", Final Report of Attorney General's Committee on Administrative Procedure, quoted with approval in *Pierce Auto Freight Lines v. Flagg*, 159 P. (2) 162, p. 177 (Sup. Ct. Oregon). It was clear reversible error for the Commission to receive hearsay evidence in support of its witness Dr. Case (Opinion Vol. I, N. R. 321) and yet to arbitrarily refuse to consider all these authoritative textual authorities particularly here where Petitioner's immediately valuable property rights in the trade name and good will of its product and the public's interest in the full benefit of an attested therapeutic product were both at stake and where "Due process requires an evaluation based on a disinterested inquiry pursued in the spirit of science"; *Rochin v. California*, 342 U. S. 165, p. 172.

Finally, the complete answer to the Commission's assertions (its Brief, pp. 62-63) concerning Petitioner's alleged failure to make "proper" application to introduce the new Twiss experiments is set out at page 2 of this Reply Brief.

No. 15373

In the United States Court of Appeals
for the Ninth Circuit

CARTER PRODUCTS, INC., PETITIONER

v.

FEDERAL TRADE COMMISSION, RESPONDENT

PETITION FOR THE ENJOIN OF AN ORDER TO CEASE AND
DESIST

RESPONDENT'S REPLY BRIEF

EARL W. KENTNER,
General Counsel

JAMES E. CORREY,
Assistant General Counsel

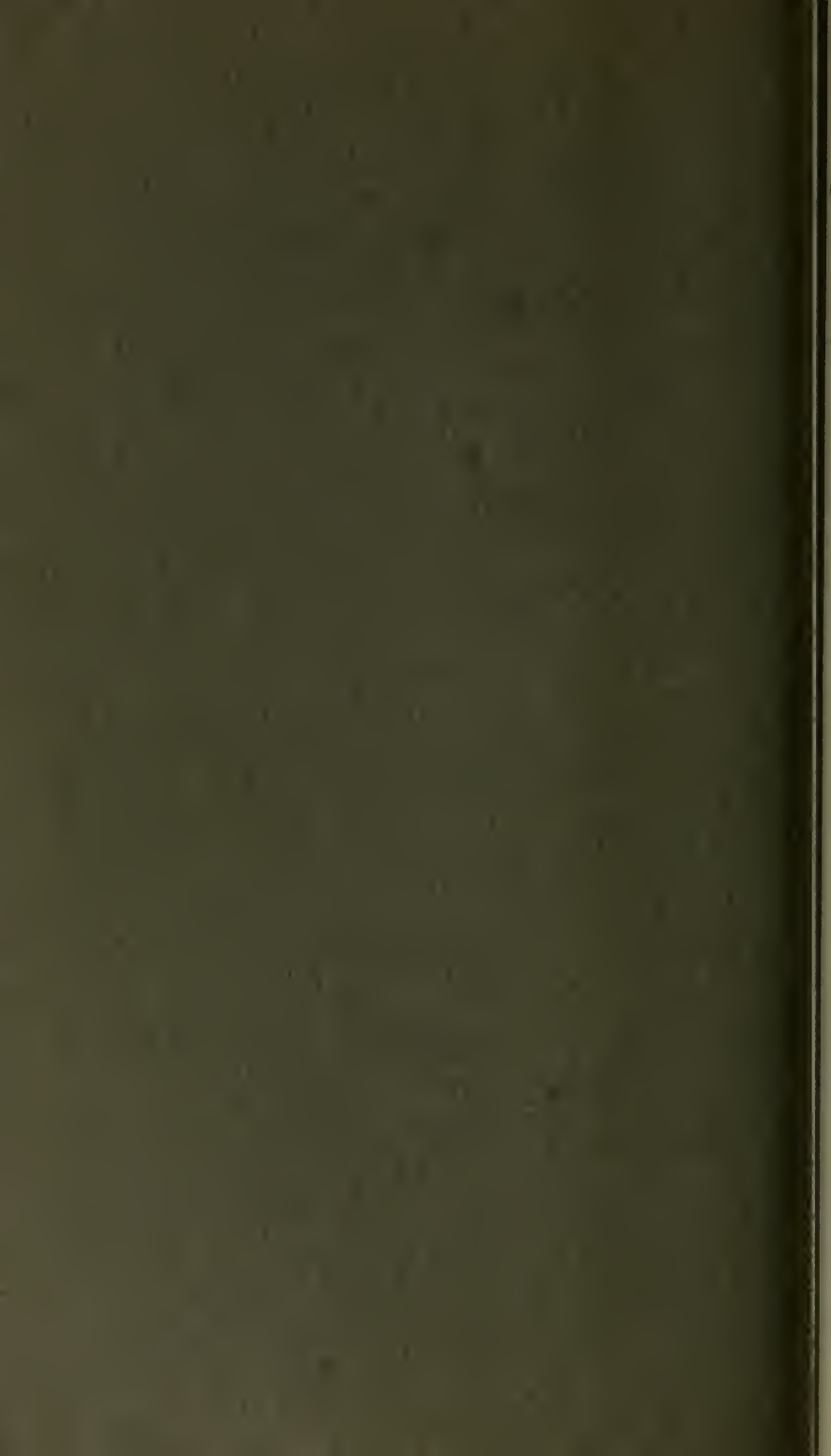
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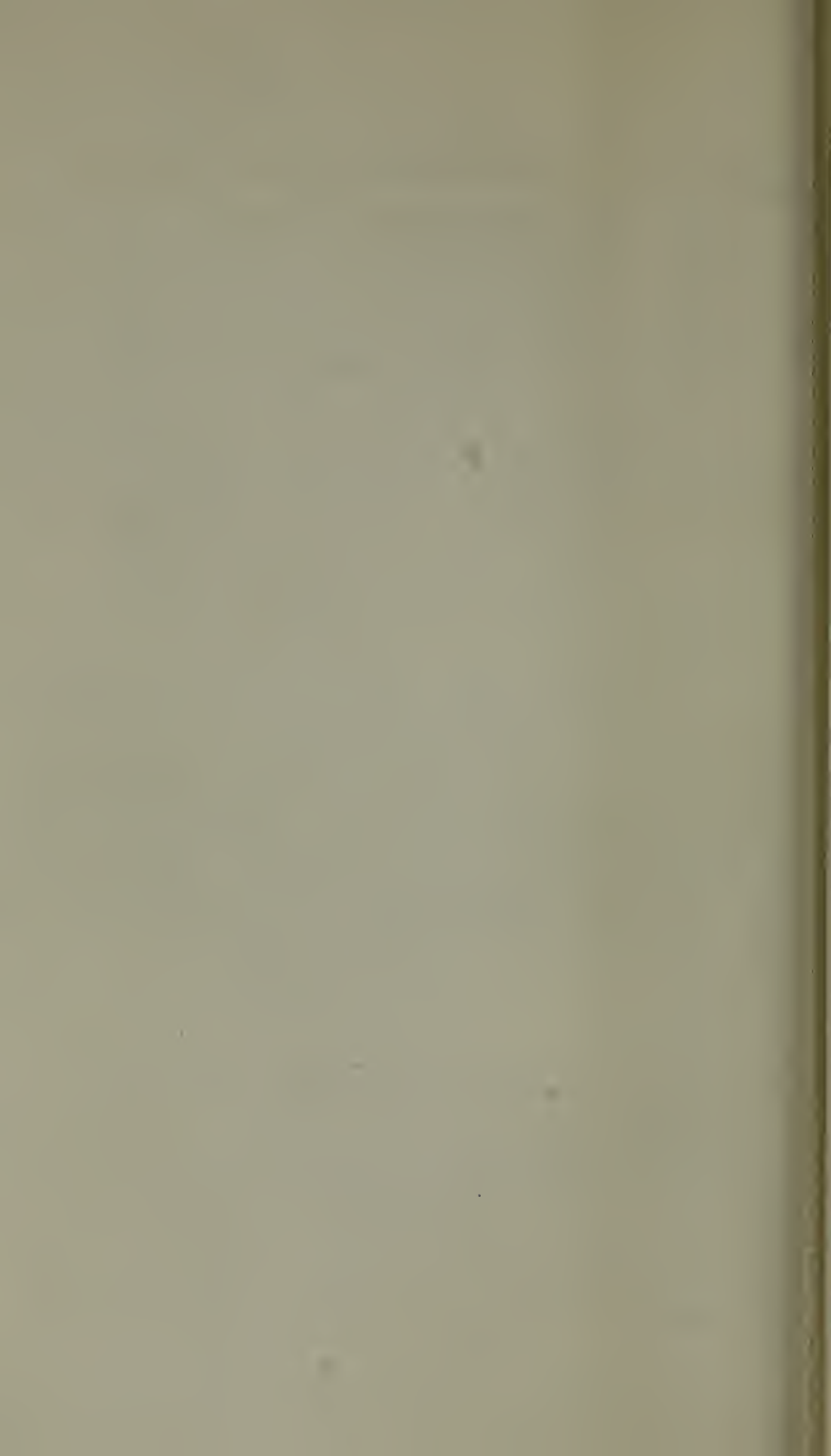
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(1)



In the United States Court of Appeals for the Ninth Circuit

No. 15373

CARTER PRODUCTS, INC., PETITIONER

v.

FEDERAL TRADE COMMISSION, RESPONDENT

*ON PETITION FOR THE REVIEW OF AN ORDER TO CEASE AND
DESIST*

RESPONDENT'S REPLY BRIEF

Respondent objected to the filing of petitioner's reply brief on the ground that it exceeded the permissible length for such a brief. The objection was overruled, though respondent was granted permission to file a brief in reply.

Normally any answer to contentions raised in a reply brief would be made in oral argument and it is not our purpose to burden the Court with a further lengthy presentation of our views. But in view of the numerous contentions made by petitioner and the express permission granted, we are constrained to set forth as concisely as possible our position with respect to the major arguments advanced in petitioner's reply brief, reserving our further answer for oral argument.

The following points we believe to be particularly deserving of answer at this time: (1) that petitioner was justified in refusing to offer in evidence the experiments conducted by Dr. Twiss (Pet. Rep. Br. 2-3); (2) that differences in general medical opinion "deprives the Commission of any power at all to issue a cease and desist order" (Pet. Rep. Br. 3); (3) that the contention of the Commission: that the only issue properly

before this Court is whether the findings that petitioner's laxative pill will have no effect on the formation or flow of bile is supported by the greater weight of the evidence, is without substance or support (Pet. Rep. Br. 6-11); (4) that the Commission flouted the "spirit and purpose" of this Court's remand (Pet. Rep. Br. 11); and (5) that there was "material misstatements, omissions and distortions contained in the Commission's brief" (Pet. Rep. Br. 1a-34a).

1. In its reply brief (p. 2) petitioner characterizes the so-called Twiss experiments as "exhaustive scientific tests carefully conducted in accordance with proper and up-to-date scientific procedures" and as "new and unanswerable body of evidence" and states in a footnote that "Because of the importance in this case of Petitioner's Motions and Offers of Proof, the Court is respectfully urged to examine them in full"; and yet, when this matter was heard on its merits by the Commission and one of the Commissioners invited petitioner to seek the introduction of this evidence by a proper motion, petitioner refused to do so (R. 15373, Vol. VIII, 3496-3497).

Petitioner says (Rep. Br. 3) that the basis for its refusal was the bias and prejudice of the examiner and that to introduce this evidence before the examiner "would constitute the merest empty gesture neither affording the Petitioner due process nor any real or adequate remedy whatsoever." That constitutes neither a valid nor a legal basis justifying petitioner's refusal to introduce into the record the experiments conducted by Dr. Twiss.

At the close of taking testimony on remand, petitioner filed a motion before the Commission seeking to void the entire proceedings on the ground that the examiner was biased and prejudiced (R. 15373, Vol. I, 146-201). Prior to the argument of this case on the merits, the Commission denied that motion and determined that the examiner was not biased and prejudiced (*id.* at 245-257). The Commissioners offered petitioner an opportunity to introduce the experiments of Dr. Twiss and evidence relating thereto. Petitioner refused to do so on the ground that the examiner was biased and prejudiced. When petitioner takes upon itself the responsibility of refusing to introduce into the record evidence which it claims to be ma-

terial and essential to a proper determination of the issues in this case, it does so at its own peril, particularly when the reason upon which the refusal is based already has been determined by the tribunal to whom such evidence is to be presented for consideration and final evaluation.

Also, as we stated in our main brief (59), the procedure under which this case was heard limited the authority of the examiner to filing with the Commission a report and recommendation—the final determination of the issues was made by the Commission. Even if the examiner was prejudiced and biased as petitioner claimed, such bias and prejudice would not and did not justify petitioner's refusal to present his case to the Commission. Having been offered an opportunity to properly place this evidence in the record and not having taken advantage of this opportunity, petitioner should not now be heard to complain.

2. Petitioner's statement (Rep. Br. 3) that differences in general medical opinion “* * * deprives the Commission of any power at all to issue a cease and desist order * * *” is utterly ridiculous. Petitioner says in effect that a conflict in the testimony of expert witnesses, automatically revokes the authority granted the Commission by Congress, to order the discontinuance of unfair methods of competition or unfair or deceptive acts or practices. But the only requirement of the Act as to the findings made by the Commission is that they must be supported by substantial evidence. The legislative history discussed by petitioner is neither relevant to, nor does it have any bearing upon, the plain language of the statute as finally enacted.

On the basis of competent, credible, expert testimony and upon the results of scientific experiment and tests properly conducted by qualified experts, the Commission found that petitioner's laxative pill will have no effect on the formation or flow of bile. The courts, including this Court, have repeatedly held that findings so supported are conclusive and will support an order to cease and desist notwithstanding the fact that they relate to matters upon which there is a conflict of expert medical opinion. In *Irwin v. Federal Trade Commission*, 143 F. 2d 316, 323 (C. A. 8, 1944), rehearing denied

July 17, 1955, the court said: “* * * But the evidence as a whole presented for determination of the issue of fact whether the representations were false, misleading or deceptive as charged. Such determination requires consideration of the testimony of the experts and decision upon conflicts between them in a field where there are few absolutes readily demonstrable. But such difficulties suggest no reason to deny the Commission’s power to resolve the fact issue.”

In *Alberty v. Federal Trade Commission*, 118 F. 2d 669 (C. A. 9, 1941), rehearing denied April 21, 1941, cert. denied 314 U. S. 630, this Court said at page 670: “The Commission’s findings are supported in part by the testimony of experts adhering to the homeopathic school, in part by the testimony of other experts. Conflicts in the testimony were for the Commission, not this court, to resolve. (Cases cited.) We cannot say that, in resolving such conflicts, the Commission acted arbitrarily.”

In *J. E. Todd, Inc. v. Federal Trade Commission*, 145 F. 2d 858 (C. A. D. C. 1944), the Court said: “The supporting evidence is substantial though the experts who gave it had no clinical experience with the product and the opposing experts had such experience.”

That the Commission has the authority to resolve conflicts in expert medical testimony has been determined in numerous cases.¹

3. In its petition for review and in its statement of points relied upon, petitioner challenges generally the findings made by the Commission. It was, and still is, the position of the

¹ See *John J. Fulton Co. v. Federal Trade Commission*, 130 F. 2d 85, 86 (C. A. 9, 1942), cert. denied November 9, 1942; *Aronberg v. Federal Trade Commission*, 132 F. 2d 165, 170 (C. A. 7, 1942); *D. D. D. Corporation v. Federal Trade Commission*, 125 F. 2d 679, 680-682 (C. A. 7, 1942); *Dr. W. B. Caldwell, Inc. v. Federal Trade Commission*, 111 F. 2d 889, 891 (C. A. 7, 1940); *Neff v. Federal Trade Commission*, 117 F. 2d 495, 497 (C. A. 4, 1941); *Justin Haynes & Co. v. Federal Trade Commission*, 105 F. 2d 988-989 (C. A. 2, 1939), cert. denied 308 U. S. 616 (1939). See also *Federal Trade Commission v. Raladam Company*, 283 U. S. 643, 646 (1931), in which, as appears from the decision below, *Raladam Company v. Federal Trade Commission*, 42 F. 2d 430, 433-435 (C. A. 6, 1930), there was substantial conflict in the evidence of medical experts. This was also true in *Federal Trade Commission v. Raladam Company*, 316 U. S. 149 (1942), although not apparent from the report of the case in the Supreme Court or the court below.

Commission that such challenge was so general in its nature and the errors claimed so vague and indefinite that the Commission could not be expected to set up straw men just to knock them down. This Court said in *North Whittier Heights Citrus Assn. v. National Labor Relations Board*, 108 F. 2d 76 (C. A. 9, 1940), cert. denied 310 U. S. 632 (1940), at page 83: "We need not consider this point for the reason that petitioner does not point to any single instance in the record supporting the assertion. We are not compelled to search the record for undesignated error claimed upon an omnibus assertion." In the absence of such designation, the Commission's findings are presumed to be "supported by substantial evidence," *Federal Trade Commission v. A. McLean & Son*, 84 F. 2d 910, 911 (C. A. 7, 1936), cert. denied 299 U. S. 590 (1936).

Furthermore, rule 18 (2) (d) of the Rules of this Court provide, inter alia, that petitioner's brief shall contain "... a specification of errors which shall be numbered"; that "... when findings are specified as error, the specification shall state as particular as may be wherein the findings of fact and conclusions of law are alleged to be erroneous . . ." In its main brief (pp. 6-10), petitioner set forth 12 numbered paragraphs under the heading "Specification of Errors and Summary of Argument." Specifications numbered 1 through 9 begin with the phrase "The Commission's findings." This phrase standing alone includes all findings of fact made by the Commission. However, when read in connection with the summary under each specification, it is plainly apparent, as the Commission pointed out in its main brief at page 12, that in specifications 1 through 8² petitioner contended that the findings are erroneous because of the alleged method and manner in which the Commission considered or failed to consider the testimony and other evidence relating to experiments and tests conducted by experts for the Commission and for petitioner. All of this evidence relates specifically to and was admitted in the record as responsive to the issue raised by the pleading as to the effect of petitioner's laxative pill upon bile production and flow.

² Specification 9 has to do with the issue of a fair and impartial hearing.

In its opening brief (10-168), petitioner developed its argument under three points. Its entire argument, except that portion devoted to the issue of a fair hearing, was directed only to the findings made by the Commission in reference to the effect of petitioner's laxative pill upon the production and flow of bile. There is not a single statement in its entire argument that refers to the numerous other findings made by the Commission. Petitioner contended that the findings in reference to the effect of its laxative pill upon the flow of bile were erroneous because of the method and manner in which the Commission considered or did not consider the evidence and testimony in reference thereto. Faced with a lengthy brief containing argument relating solely to certain specific and designated findings, the Commission could not reasonably be expected to do more than answer that argument and certainly could infer that petitioner had abandoned any claim of error with respect to the numerous other findings. The Commission, therefore, limited its argument to the sole issue raised and argued by petitioner.

In *Moore v. Tremelling*, 100 F. 2d 39, 43 (C. A. 9, 1938), the Court said: "Appellants' assignment of error . . . relating to the correctness of the Court's instruction on the statute of limitations not being argued or discussed in the brief is abandoned." And in *Radius v. Travelers Insurance Co.*, 87 F. 2d 412, 413 (C. A. 9, 1937), this Court said: "The appellant's assignment of error contains eight assignments, of which four are set out in appellant's brief. The four not pressed in the brief are deemed abandoned and will not be considered"; also, see *Donnelly v. United States*, 376 U. S. 505, 511 (1928); *Eastman Kodak Co. v. Southern Photo Materials Co.*, 273 U. S. 359, 369 (1927).

In *Peck v. Shell Oil Co.*, 142 F. 2d 141 (C. A. 9, 1944), this Court said at page 143: "With respect to many of the 'points' stated by appellants no argument or discussion is presented in their opening brief. Therefore, those 'points' are deemed abandoned and need not be considered herein" and cases cited therein.

In *Stetson v. United States, et al.*, 155 F. 2d 359, 360 (C. A. 9, 1946), this Court said: "Errors assigned but not argued are deemed waived," citing cases in footnote 5. Also see *Western*

Nat. Ins. Co. v. Le Clare, 163 F. 2d 337, 340 (C. A. 9, 1947), rehearing denied October 24, 1947. In 5 Federal Digest, pages 218-229, numerous cases are cited in support of this proposition.

We do not contend, of course, that this Court does not have the authority and power *sua sponte* to consider and determine every issue raised below by the pleadings, whether such issues are argued by petitioner or not but we do point out that in the absence of good and compelling reasons to the contrary (none of which exist here), not only has this Court but all other Courts of Appeals and the Supreme Court of the United States, limited consideration to the issues actually briefed and argued by a petitioner.

While we are confident that the only issue properly before the Court is that which relates specifically to the effect of petitioner's laxative pill upon the production or flow of bile, we are equally confident that the Commission's findings as to the other false and misleading representations made by petitioner are supported by substantial evidence. (See *infra*. 16-17.) During the examination of medical experts placed on the stand by counsel in support of the complaint, and in some instances by petitioner's counsel, counsel supporting the complaint examined the witnesses as to the various exhibits containing the representations as to the therapeutic value of its laxative pills, which were admittedly disseminated by petitioner, and asked them whether such representations were true or false.³ In each instance, the witness replied that they were false. Except as to the representation that petitioner's laxative will affect the production or flow of bile, petitioner's counsel made no effort whatever to establish the truth of the other representations made in petitioner's advertisements as to the therapeutic value of its laxative pill.

4. Petitioner's contention that the Commission flouted the spirit and purpose of this Court's remand is wholly without foundation. The Commission speaking through Commissioner

³ For example, see R. 12940, Vol. III, 934 in which petitioner's witness, Dr. Sanford, testified that he thought the representation contained in petitioner's advertisement (CX 1-13) "is all hooey"; see also R. 12940, Vol. I, 386-391.

Kern, stated its position as to the requirement placed upon the Commission by this remand. Commissioner Kern said (R. 15373, Vol. I, 324):

It seems obvious to us, therefore, that the reason for the Court's action setting aside the Commission's order to cease and desist was that the respondent had been denied a fair hearing before the Commission in that the hearing examiner unduly and prejudicially restricted the respondent's [petitioner's] right to cross-examine Doctors Bollman, Lockwood and Case. It seems equally obvious that the purpose and effect of the remand was to enable the Commission to correct the errors in this respect by recalling these witnesses for full cross-examination. This the Commission has undertaken in good faith to do. At a hearing held in Santa Barbara, California, Doctor Case had been recalled to the stand and tendered to the respondent for further cross-examination. After 130 pages of testimony had been received, the respondent's [petitioner's] counsel had announced "I have asked all the questions I want to ask" (R. 10838). At a subsequent hearing held in Washington, D. C., Doctor Bollman had been recalled to the stand and thereafter further cross-examined. After 268 pages of testimony had been received, the respondent's [petitioner's] counsel had again announced "I have no [further] questions" (R. 11193). Doctor Lockwood, the third witness the Court held had been improperly curtailed, had, in the meantime, died. In view of his unavailability for further cross-examination all of his testimony and all exhibits theretofore offered in support thereof had been, on the respondent's [petitioner's] motion, stricken from the record. Thus the purpose and intent of the remand had been fully served. The additional matters proffered by the respondent [petitioner] essentially constituted cumulative evidence similar in vein to that introduced by the respondent [petitioner] at the original hearings. They were in no sense within the purview of the Court's remand to the Commission or the Commission's remand to the hearing examiner, neither of which con-

templated use of the supplemental hearings for retrial of the issues and matters as to which full hearing or opportunity therefor had been afforded in the original hearings, and the hearing examiner's action in rejecting this additional evidence is not regarded as erroneous.

In *Labor Board v. Donnelly Garment Co.*, 330 U. S. 219 (1947) (one of the cases cited by the Supreme Court in its order granting certiorari), the Court said at pages 225-226: "This second hearing was not a new proceeding . . . The Board [National Labor Relations Board] was justified in not deeming itself under duty to grant a 'new trial' . . ."; and at page 228 said: "Due process does not afford a party the right to treat as a rehearing a hearing on the issues for which the hearing was adequate . . . Since in our view the remand did not call for a proceeding *de novo*, the Board was not required to reopen any issue as to which its ruling was left unassailed by the Circuit Court of Appeals in its first decision . . ."

It was upon the basis of the decision of the Supreme Court in the Donnelly case that the Commission expressed its opinion as hereinabove set forth that the remand did not contemplate the retrial of issues and matters left unassailed by the decision of this Court setting aside the Commission's order to cease and desist. We submit that it cannot reasonably be said, as petitioner does, that the Commission has flouted the spirit and purpose of the order of this Court remanding this case to the Commission.

5. We shall take up, *seriatim*, the points set forth in that portion of petitioner's reply brief designated Appendix A. In order to avoid repetition in making such comment we point out to the Court that petitioner in its Appendix (4a, 6a, 8a, 11a, 12a, 13a, 14a, 17a, 19a, 20a and 31a) constantly cites excerpts from "Textual Authorities" as if such authorities had been admitted into evidence and relies upon them to sustain its contention that the Commission has omitted in its main brief evidence establishing certain facts. These "textual authorities" are not in evidence. Some were marked for identification and some are part of petitioner's offers of proof.

1. No comment.

2. Petitioner quotes the testimony of Dr. Bollman (Rep. Br. 1a) in referring to the statement made by the Commission in its main brief (Res. Br. 16) that if there is an impairment of the liver which cuts the production of bile 80%, there still would remain sufficient bile for the proper digestion of fat food. Actually the testimony of Dr. Bollman quoted by petitioner establishes the truth of the statement. It is uncontradicted in the record that a liver so damaged or impaired is capable of producing sufficient bile to carry on the digestion of fat foods (R. 12940, Vol. IV, 1417, 1478, 1556-1557).

Whether Dr. Morrison knew or did not know of any ambulatory cases of individuals whose livers were 80% deficient is wholly immaterial.

3. Petitioner states (Rep. Br. 4a-5a) that when the Commission told the Court (Res. Br. 16) "an individual does not require the production of 2 pints of bile daily to prevent digestive disturbances," the Commission failed to also tell the Court that Dr. Palmer testified that one of the functions of the liver is to excrete 2 pints of bile into the bowels each day. But this testimony of Dr. Palmer does not affect the statement made. The amount of bile that the liver normally excretes and the amount of bile that is essential to digest fat foods are entirely different. It is uncontradicted in the record that 2 pints of bile daily are not necessary to the digestion of fat foods (R. 12940, Vol. II, 673-674).

Furthermore Dr. Palmer himself testified that the statement appearing in one of petitioner's advertisements, "It takes those good old Carter's Little Liver Pills to get those 2 pints flowing freely," was false and just propaganda (R. 15373, Vol. II, 648).

4. Petitioner using the testimony of Dr. Morrison also attacks (Rep. Br. 5a-6a) the statement made by the Commission (Res. Br. 16) to the effect that there is no evidence that any doctor ever prescribed petitioner's laxative pills for any purpose other than to produce an evacuation of the bowels.

An analysis of Morrison's testimony, however, establishes that insofar as petitioner's laxative pill is concerned, he used them only when biliary dyskinesia "was associated with chronic

constipation." And, it is obvious, therefore, that when he did use the pills, it was for the purpose of producing an evacuation of the bowels.

5. No written comment deemed necessary. Comment, if required, will be made during oral argument.

6. No written comment deemed necessary. Comment, if required, will be made during oral argument.

7. No written comment deemed necessary. Comment, if required, will be made during oral argument.

8. In its reply brief (13a-14a) petitioner refers to the testimony of Dr. Ivy in an effort to convince this Court that because Dr. Ivy testified that duodenal drainages are reliable for testing a "potent stimulant", that this testimony in some manner established the fact that aloes and podophyllum, the ingredient of petitioner's laxative pill, are potent stimulants. Nothing could be further from the truth. Dr. Ivy testified as follows:

Q. Doctor, what do you mean by the expression "potent substance"?

A. An active substance.

Q. Do you consider Carter's Little Liver Pills or aloes or podophyllum as such?

A. Not for promoting the flow of bile into the duodenum. They are potent as far as laxation is concerned (R. 12940, Vol. IV, 1537).

9. No written comment deemed necessary. Comment, if required, will be made during oral argument.

10. No written comment deemed necessary. Comment, if required, will be made during oral argument.

11. Petitioner (Rep. Br. 16a-17a) once more seeks to have this Court weigh the evidence in the case. We have hereinbefore pointed out this function belongs to the Commission and not the Court.

Petitioner states (Rep. Br. 16a-17a) that it was foreclosed from the proper cross-examination of Commission's witness Ivy which, according to petitioner, would have demonstrated that Dr. Ivy virtually admitted that the test animals had "reached the peak of their ability to put out any further bile in response to the administration, on top of these bile salts,

of doses of petitioner's product." A short reply to this is that the matter found on pages 18 and 19 of petitioner's opening brief, cited by petitioner in support of its contention here, has nothing whatever to do with the administration of bile salts to the test animals. Not knowing exactly to what petitioner refers, we are unable to reply. However, Dr. Ivy testified that dogs of the weights used by him in his experiments normally would excrete from 8 to 10 grams of bile salts daily. He further testified that this ability to excrete this amount of bile salts a day was far in excess of the 2 grams of bile salts which he administered to these dogs each day (R. 12940, Vol. IV, 1562-1563).

It is true that the particular experiments of Dr. Ivy, to which petitioner refers (Rep. Br. 17a), were concerned only with the determination of the possible effect of petitioner's laxative pill on the formation of bile by the liver (choleretic effect). However, other experiments performed by Dr. Ivy, as well as those performed by other scientists, and the opinion testimony of experts, all of which we discussed in our brief (Res. Br. 42-51), demonstrate that the pills also had no effect on increasing the flow of bile "by facilitating gall bladder evacuation" (chologogic effect). Furthermore, other evidence in the record which we discussed (Res. Br. 51-54) uncontradictedly prove that the pills had no effect on promoting the flow of bile by any other means. Thus, the overwhelming weight of the evidence in the record—for the most part uncontradicted—is that petitioner's laxative pill has no effect on *either the formation or flow of bile*.

12. Petitioner tells the Court (Rep. Br. 17a) that the Commission in its main brief (33) quoted Dr. Crandall as testifying "that he did not think constipation under any circumstances decreased the flow of bile to such an extent as to affect the digestive process." Petitioner is in error when it claims that the Commission quoted the testimony of Dr. Crandall. Actually the Commission gave what it thought to be a fair summary of the following testimony of Dr. Crandall appearing in Record 12940, Volume IV, page 1672:

Q. Doctor, do you think that constipation under any circumstances decreases the flow of bile to such an ex-

tent that there is not sufficient bile in the duodenum to carry on the function of bile in the human digestive process?

A. No.

Q. Would you say that it [constipation] would decrease either [sic] the secretion of bile to such an extent that there would not be sufficient bile in the system to carry on the function of the bile?

A. I know of no evidence to indicate that.

In the testimony of Dr. Crandall quoted by petitioner in its reply brief (17a), Dr. Crandall merely stated that he thought constipation *might* decrease the flow of bile. This testimony in no way contradicts his former testimony that even if such decrease appeared, there would still be sufficient bile to carry on its function in the digestive process.

13. Petitioner states (Rep. Br. 19a) that the Commission gave no record references to support the statement that Dr. Ivy conducted a second series of experiments "after the effect of the above experiments on the dogs had worn off." But on page 46 of the Commission's main brief, the record is referred to as follows: "R. 12940, Vol. II, 641-643." In addition to the above, petitioner complains that the animals were under the effect of anesthesia during these experiments. Due to the type of experiments, there is nothing remarkable about this. In the experiments conducted by Dr. Hazelton, petitioner's own witness, the dogs were anesthetized (R. 15373, Vol. II, 726).

14. Petitioner told the Court (Op. Br. 107) that the conditions which Dr. Killian testified to "were the very conditions in which petitioner's product was intended, designed and claimed to be of benefit." It is interesting to note that in its reply brief (21a) petitioner now tells the Court that the conditions under which its laxative pill will increase bile flow are not confined to the conditions of Dr. Killian's experiments. Obviously, petitioner is blowing hot and cold.

Petitioner complains that when Dr. Killian was endeavoring to explain that the effect of petitioner's laxative pill on bile was "not confined to the four conditions of his experiments," he was prevented from doing so by the examiner and that this

was a flat denial of petitioner's constitutional due process. It is true that at one point during the cross-examination of Dr. Killian he attempted to express an opinion when counsel supporting the complaint had not asked him for one (R. 12940, Vol. III, 1282-1285). But on redirect examination, Dr. Killian was given the opportunity to express the opinion which he had attempted to give voluntarily on cross-examination (id., 1310-1315), so there can hardly be any claim of prejudicial error.

15. Petitioner's argument (Rep. B. 22a-26a) is merely a continuation of its attack upon the experiments conducted by Dr. Ivy and goes to the credibility of Dr. Ivy's testimony and the weight to be accorded thereto. We notice, however, that the attack is similar to that petitioner made in the original case (No. 12940). In response to it the Court then said: "Petitioner also argues that fatal error was committed in admitting evidence pertaining to certain experiments on dogs and human patients. In our opinion the objection to these experiments, several of which will be mentioned hereafter, goes to their weight only, not to their credibility"; *Carter Products, Inc. v. Federal Trade Commission*, 201 F. 2d 446 (C. A. 9, 1953); see footnote 1, 448.

16. No comment deemed necessary. Comment, if required, will be made during oral argument.

17. Petitioner's contention (Rep. Br. 26a-28a) is a mere reiteration and continuation of its argument that it was denied a fair and impartial hearing. In this connection, it might be noted that in the original case (R. 12940) petitioner contended that his cross-examination of Dr. Bollman was restricted by reason of the fact that he was not permitted to ask the following question: "Whether, functionally, man and dog react to the same stimuli in the same manner." This Court agreed with petitioner's contention and held that the cross-examination of Dr. Bollman had been unjustifiably restricted by the examiner and this together with other restrictions and cross-examination resulted in the Court vacating the order to cease and desist. On remand in the instant matter when Dr. Bollman was on the stand, for some reason best known to petitioner, it did not ask Dr. Bollman this particular question.

18. The contention of petitioner (Rep. Br. 28a-30a) is that the Commission adhered to the report and recommendation of the examiner and was misled into making findings based upon the misstatements of the examiner in his original report. A complete reply to this contention of petitioner is the statement made by the Commission in its decision, which is as follows: “. . . and the matter came on for hearing on the merits before the Commission; and the Commission, *having exhaustively considered the entire record*, including the evidence adduced after remand and the briefs and oral arguments of counsel, now finds that this proceeding is in the interest of the public and makes its relevant and supplemental findings as to the facts and its conclusions drawn therefrom the same to be in lieu of its decision of March 28, 1951” (R. 15373, Vol. I, 267) (emphasis supplied).

Petitioner contends (Rep. Br. 28a) that the examiner in his original report “indulged in the misleading practice of creating a false impression in the Commission’s mind that examination of Petitioner’s own witnesses disclosed damaging admissions by them.” It states that a typical instance of this misleading practice is that the examiner, in his original report on the testimony of Dr. Killian, cited the record containing the testimony of Dr. Ivy.

Paragraph 374 of the examiner’s original report (R. 12940, Vol. I, 215-216) to which petitioner refers, is the examiner’s report on Dr. Killian’s testimony in reference to his first condition. All references to the record made by the examiner in this paragraph, except the first, were to the testimony of Dr. Killian. This report of the examiner definitely establishes the fact that *Dr. Killian did testify* (R. 12940, Vol. III, 1235-1236; see also 1249-1250) that the administration of petitioner’s laxative pill, when given over a sufficient period of time to produce laxation as set forth in his first condition, will not increase the flow of bile. This being true, the incorrect record reference could not possibly have misled the Commission as to the testimony of Dr. Killian. As a matter of fact, the incorrect record reference made by the examiner was to Dr. Ivy’s testimony and the reading of that testimony establishes the fact that Dr. Ivy also testified to the same effect as did Dr. Killian.

In an administrative procedure in which the examiner merely files a report and recommendation and has no authority and does not make any final determination of the issues, as in the instant case, any possible bias and prejudice of the examiner is immaterial.

While we feel confident that the only issues properly before the Court at this time, with reference to the false and misleading representations contained in the petitioner's advertising, are those which relate specifically to the production or flow of bile, nevertheless, the Commission's findings, as well as the injunctive provisions of the order based thereon, which concern the other misrepresentations made by petitioner, are supported by substantial evidence.

1. That the product, "Carter's Little Liver Pills," represents a fundamental principle of nature in self-treatment (R. 12940, Vol. I, 388-389); id. 896 (Dr. Lopez, petitioner's witness); id. 897 (Dr. Avrack, petitioner's witness); id. 899 (Dr. Whittemore, petitioner's witness); id. Vol. III, 931 (Dr. Leader, petitioner's witness); id. 932 (Dr. Dorman, petitioner's witness); id. 933, 934 (Dr. Sanford, petitioner's witness); id. 936 (Dr. Boyd, petitioner's witness)).

2. That said preparation will bring on or restore regularity of bowel movement, or is a cure, remedy, or competent or effective treatment for constipation, or has any beneficial value in the treatment of any of the symptoms thereof in excess of temporary relief afforded by its laxative action (R. 12940, Vol. II, 622, 649, 695, 900; R. 15373, Vol. I, 387; id. Vol. II, 695, 719, 722; see also Res. Br. 14-15).

3. That said preparation does not contain strong medicines (R. 12940, Vol. I, 350, 464, id. Vol. II, 929-930; id. Vol. III, 934 (Dr. Sanford, petitioner's witness); R. 15373, Vol. II, 648).

4. That said preparation is unqualifiedly safe (R. 12940, Vol. I, 359, 361-362; R. 15373, Vol. I, 361).

5. That said preparation is an effective treatment for sluggish liver function or that it will have any therapeutic action on any condition, disease or disorder of the liver (R. 12940, Vol. I, 366; id. Vol. II, 549; and id. Vol. II, 689-690). See also Res. Br. 11.)

6. That said preparation will provide two-way relief or that it possesses therapeutic properties in addition to those afforded by laxative action (R. 12940, Vol. I, 387-388; R. 15373, Vol. II, 649).

7. That said preparation will cause a proper flow of or beneficially affect, the gastric juices or digestive juices or lessen food decay (R. 12940, Vol. I, 379; id. II, 672-673; R. 15373, Vol. II, 622).

8. That said preparation is based on the fundamental principle of the operation of the digestive system (R. 12940, Vol. I, 378-379; id. II, 691; R. 15373, Vol. II, 628).

9. That said preparation will help food digestion, or regulate digestion or the digestive system (R. 12940, Vol. I, 379; id. II, 691; R. 15373, Vol. II, 628; see also R. 12940, Vol. VIII, 1560-1562; R. 15373, Vol. II, 622).

10. That said preparation will have any influence in inducing a state of "bounce," vigor or well-being except in those instances where a lack thereof is due solely to constipation (R. 15373, Vol. II, 622-623; id. Vol. III, 934).

11. That constipation poisons the body (R. 15373, Vol. II, 623, id. Vol. III, 945, Dr. Sanford, petitioner's witness).

12. That said preparation has any value in the treatment of headache, ugly complexion, bad breath, coated tongue, or a bad taste in the mouth, or for those conditions in which an individual feels "Down-and-out," "blue," etc., in excess of such temporary relief thereof as may be afforded by an evacuation of the bowels in those cases in which such symptoms or conditions are associated with and caused by constipation (R. 15373, Vol. I, 383; id. III, 934-935; R. 12940, Vol. III, 944-945).

13. That said preparation is a competent or effective treatment for indigestion or retarded digestion (R. 15373, Vol. I, 378-379; id. Vol. IV, 1560-1562).

14. That said preparation is a competent or effective treatment for biliousness (R. 12940, Vol. II, 691-692; R. 15373, Vol. I, 397-398).

CONCLUSION

The Commission, therefore, prays that the petition to review be dismissed and that the Court enter a decree affirming the

Commission's order to cease and desist and commanding petitioner to obey the same and comply therewith.

Respectfully submitted.

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WASHINGTON, D. C., DECEMBER 30, 1957.